

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

IN RE: JOHNSON & JOHNSON  
TALCUM POWDER PRODUCTS

MARKETING, SALES PRACTICES AND )  
PRODUCTS LIABILITY LITIGATION )

MDL Docket No. 2738

## This Document Relates To All Cases

**DEFENDANTS JOHNSON & JOHNSON AND JOHNSON & JOHNSON  
CONSUMER INC.'S REPLY IN SUPPORT OF MOTION TO EXCLUDE  
PLAINTIFFS' EXPERTS' ASBESTOS-RELATED OPINIONS**

**DRINKER BIDDLE & REATH LLP**  
*A Delaware Limited Liability  
Partnership*  
600 Campus Drive  
Florham Park, New Jersey 07932  
(973) 549-7000

SKADDEN, ARPS, SLATE,  
MEAGHER & FLOM LLP  
1440 New York Avenue, N.W.  
Washington, D.C. 20005  
(202) 371-7000

*Attorneys for Defendants Johnson &  
Johnson and Johnson & Johnson  
Consumer Inc.*

## **TABLE OF CONTENTS**

	<b><u>Page</u></b>
INTRODUCTION .....	1
ARGUMENT .....	4
I. DRS. LONGO AND RIGLER’S OPINIONS SHOULD BE EXCLUDED BECAUSE THEY REDEFINE “ASBESTOS” FOR LITIGATION PURPOSES.....	4
A. Plaintiffs Misrepresent Health And Regulatory Bodies’ Definitions Of Asbestos In Attempting To Defend Dr. Longo’s Litigation Definition.....	5
B. Drs. Longo And Rigler’s Definition Of Asbestos Is Inapposite Because It Is Different From That Of Plaintiffs’ Causation Experts.....	14
II. PLAINTIFFS FAIL TO REFUTE THAT DRS. LONGO AND RIGLER’S MICROSCOPIC ANALYSIS WAS UNRELIABLE.....	16
A. Plaintiffs Fail To Show That Drs. Longo And Rigler’s Visual TEM Analysis Was Reliable.....	20
B. Plaintiffs Fail To Show That Drs. Longo And Rigler’s SAED Analysis Was Reliable. ....	28
C. Plaintiffs Fail To Show That Drs. Longo And Rigler’s EDXA Analysis Was Reliable. ....	34
D. Plaintiffs Fail To Show That Drs. Longo And Rigler’s PLM Analysis Was Reliable. ....	39
III. PLAINTIFFS HAVE NO SUPPORT FOR THE THEORY THAT THE LEVELS AND TYPES OF ASBESTOS ALLEGED TO BE PRESENT IN THE PRODUCTS CAUSE OVARIAN CANCER.....	43
A. Plaintiffs Have Offered No Evidence That The Levels Of Asbestos Alleged By Drs. Longo And Rigler Could Possibly Cause Ovarian Cancer.....	45

B.	Plaintiffs’ Experts’ Opinions Regarding Asbestos Are Unreliable Because They Are Based On Studies Regarding Types Of Asbestos That Plaintiffs’ Experts Did Not Claim To Identify In The Products.....	49
C.	Plaintiffs’ “Any Exposure” Theory Of Causation Is Unscientific And Unreliable. ....	51
IV.	PLAINTIFFS LACK RELIABLE SCIENTIFIC EVIDENCE THAT ASBESTOS WAS PRESENT IN THE TALC ORE USED TO SOURCE THE PRODUCTS.....	52
A.	Plaintiffs’ Experts’ Opinions Regarding The Alleged Presence Of Asbestos In Talc Ore Are Not Supported By The Data On Which They Rely.....	53
1.	Drs. Cook And Krekeler Unreliably Base Their Opinions On Counsel-Generated Collections And Summaries Of Documents. ....	53
2.	The Counsel-Selected Documents On Which Drs. Cook And Krekeler Rely Do Not Provide A Reliable Basis For Their Conclusions. ....	57
B.	Dr. Krekeler Lacks A Reliable Basis For His Opinions That Cleavage Fragments Are “Asbestiform Particles” That Carry Health Risks For Humans. ....	61
	CONCLUSION .....	64

## **TABLE OF AUTHORITIES**

### **Page(s)**

### **CASES**

<i>Amorgianos v. National Railroad Passenger Corp.</i> , 303 F.3d 256 (2d Cir. 2002) .....	18, 30, 32
<i>Anderson v. Bristol Myers Squibb Co.</i> , No. Civ.A. H-95-0003, 1998 WL 35178199 (S.D. Tex. Apr. 20, 1998) .....	60
<i>Aycock v. R.J. Reynolds Tobacco Co.</i> , 769 F.3d 1063 (11th Cir. 2014) .....	47
<i>In re Baycol Products Litigation</i> , 532 F. Supp. 2d 1029 (D. Minn. 2007) .....	60
<i>B.H. ex rel. Holder v. Gold Fields Mining Corp.</i> , No. 04-CV-0564-CVE-PJC, 2007 WL 188130 (N.D. Okla. Jan. 22, 2007) .....	12, 22
<i>Bowers v. National Collegiate Athletic Association</i> , 564 F. Supp. 2d 322 (D.N.J. 2008) .....	60
<i>Bracco Diagnostics, Inc. v. Amersham Health, Inc.</i> , 627 F. Supp. 2d 384 (D.N.J. 2009) .....	33, 43
<i>Bruno v. Bozzuto's, Inc.</i> , 311 F.R.D. 124 (M.D. Pa. 2015) .....	17
<i>Caraker v. Sandoz Pharmaceuticals Corp.</i> , 172 F. Supp. 2d 1046 (S.D. Ill. 2001) .....	13
<i>Childress v. Johnson &amp; Johnson</i> , No. 2:12-cv-01564, 2017 WL 6348621 (S.D. W. Va. Dec. 12, 2017) .....	47
<i>Citizens Financial Group, Inc. v. Citizens National Bank of Evans City</i> , 383 F.3d 110 (3d Cir. 2004) .....	17

<i>Crowley v. Chait</i> , 322 F. Supp. 2d 530 (D.N.J. 2004).....	56
<i>Daubert v. Merrell Dow Pharmaceuticals, Inc.</i> , 43 F.3d 1311 (9th Cir. 1995) .....	19
<i>Daubert v. Merrell Dow Pharmaceuticals, Inc.</i> , 509 U.S. 579 (1993).....	13
<i>In re Diet Drugs</i> , No. MDL 1203, 2001 WL 454586 (E.D. Pa. Feb. 1, 2001) .....	41
<i>Disabled in Action v. City of New York</i> , 360 F. Supp. 3d 240 (S.D.N.Y. 2019) .....	18, 35
<i>E.E.O.C. v. Freeman</i> , 778 F.3d 463 (4th Cir. 2015) .....	58
<i>Eghnayem v. Boston Scientific Corp.</i> , 57 F. Supp. 3d 658 (S.D. W. Va. 2014) .....	18
<i>Finestone v. Florida Power &amp; Light Co.</i> , No. 03-14040-CIV, 2006 WL 267330 (S.D. Fla. Jan. 6, 2006) .....	60
<i>Florida Power &amp; Light Co. v. Qualified Contractors, Inc.</i> , No. 04-80505-Civ, 2005 WL 5955702 (S.D. Fla. Dec. 6, 2005) .....	19
<i>General Electric Co. v. Joiner</i> , 522 U.S. 136 (1997).....	60
<i>Glastetter v. Novartis Pharmaceuticals Corp.</i> , 252 F.3d 986 (8th Cir. 2001) .....	9
<i>Hanson v. Colgate-Palmolive Co.</i> , 353 F. Supp. 3d 1273 (S.D. Ga. 2018) .....	passim
<i>Heller v. Shaw Industries, Inc.</i> , 167 F.3d 146 (3d Cir. 1999) .....	61
<i>Holbrook v. Lykes Brothers Steamship Co.</i> , 80 F.3d 777 (3d Cir. 1996) .....	47

<i>Kim v. Crocs, Inc.</i> , No. 16-00460 JAO-KJM, 2019 WL 923879 (D. Haw. Feb. 25, 2019).....	22
<i>Kumho Tire Co. v. Carmichael</i> , 526 U.S. 137 (1999).....	17
<i>Moore v. Ashland Chemical Inc.</i> , 151 F.3d 269 (5th Cir. 1998) .....	19
<i>Nilssen v. Motorola, Inc.</i> , No. 93 C 6333, 1998 WL 851493 (N.D. Ill. Dec. 1, 1998).....	13
<i>In re Paoli Railroad Yard PCB Litigation</i> , 35 F.3d 717 (3d Cir. 1994) .....	16, 41
<i>Rider v. Sandoz Pharmaceuticals Corp.</i> , 295 F.3d 1194 (11th Cir. 2002) .....	9
<i>Ruffin v. Shaw Industries, Inc.</i> , 149 F.3d 294 (4th Cir. 1998) .....	22
<i>Snodgrass v. Ford Motor Co.</i> , No. 96-1814(JBS), 2002 WL 485688 (D.N.J. Mar. 28, 2002).....	33
<i>Soldo v. Sandoz Pharmaceuticals Corp.</i> , 244 F. Supp. 2d 434 (W.D. Pa. 2003) .....	16
<i>State Farm Fire &amp; Casualty Co v. Electrolux Home Products, Inc.</i> , 980 F. Supp. 2d 1031 (N.D. Ind. 2013).....	56
<i>Tamraz v. Lincoln Electric Co.</i> , 620 F.3d 665 (6th Cir. 2010) .....	13
<i>In re TMI Litigation</i> , 193 F.3d 613 (3d Cir. 1999) .....	41
<i>In re TMI Litigation Cases Consolidated II</i> , 911 F. Supp. 775 (M.D. Pa. 1996).....	21
<i>Truck Insurance Exchange v. MagneTek, Inc.</i> , 360 F.3d 1206 (10th Cir. 2004) .....	18

<i>United States v. Hebshie</i> , 754 F. Supp. 2d 89 (D. Mass. 2010).....	38
<i>United States v. Schultz</i> , No. 14-cr-467-3, 2016 WL 7409911 (N.D. Ill. Dec. 22, 2016) .....	35
<i>United States v. Tuzman</i> , No. 15 Cr. 536 (PGG), 2017 WL 6527261 (S.D.N.Y. Dec. 18, 2017) .....	18
<i>Wessmann v. Gittens</i> , 160 F.3d 790 (1st Cir. 1998).....	18
<i>Zenith Electronics. Corp. v. WH–TV Broadcasting Corp.</i> , 395 F.3d 416 (7th Cir. 2005) .....	38
<i>In re Zicam Cold Remedy Marketing, Sales Practices &amp; Products Liability Litigation</i> , No. 09-md-2096-PHX-FJM, 2011 WL 798898 (D. Ariz. Feb. 24, 2011).....	9
<i>In re Zoloft (Sertraline Hydrochloride) Products Liability Litigation</i> , 858 F.3d 787 (3d Cir. 2017) .....	17, 18, 34

## RULE

Fed. R. Civ. P. 26(a)(2)(B) .....	13
-----------------------------------	----

## REGULATIONS

29 C.F.R. § 1910.1001(b) .....	6
30 C.F.R. § 71.702(a).....	6
30 C.F.R. Parts 56, 57, and 71 .....	6
40 C.F.R. § 61.141 .....	6, 8
40 C.F.R. § 763.163 .....	6, 8
Asbestos Exposure Limit; Final Rule, 73 Fed. Reg. 11,284 (MSHA Feb. 29, 2008) .....	6, 23

Occupational Exposure to Asbestos, Tremolite, Anthophyllite and Actinolite, 57 Fed. Reg. 24,310 (OSHA June 8, 1992).....	6, 7, 8
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Acheson et al., <i>Mortality of Two Groups of Women Who Manufactured Gas Masks from Chrysotile and Crocidolite Asbestos: A 40-Year Follow-Up</i> , 39 Br J Ind Med 344 (1982) .....	48
Blount, <i>Amphibole Content of Cosmetic and Pharmaceutical Talcs</i> , 94 Env't'l Health Perspectives 225 (1991).....	38
Camargo et al., <i>Occupational Exposure to Asbestos and Ovarian Cancer: A Meta-Analysis</i> , 119 Env'tl. Health Perspectives 1211 (2011) .....	46, 50
Heller et al., <i>Asbestos Exposure and Ovarian Fiber Burden</i> , 29(5) Am. J. of Industrial Med. 435 (1996) .....	44
Huncharek & Muscat, <i>Perineal Talc Use and Ovarian Cancer Risk: A Case Study of Scientific Standards in Environmental Epidemiology</i> , 20 Eur. J. Cancer Prev. 501 (2011).....	52
Huncharek et al., <i>Use of Cosmetic Talc on Contraceptive Diaphragms and Risk of Ovarian Cancer: A Meta-Analysis of Nine Observational Studies</i> , 16 Eur. J. Cancer Prev. 422 (2007).....	52
Int'l Agency for Research on Cancer, World Health Org., <i>100 Monographs on the Evaluation of Carcinogenic Risks to Humans: Arsenic, Metals, Fibres, and Dusts</i> 220 (2012).....	46, 50



Int'l Agency for Research on Cancer, World Health Org., 93 <i>Monographs on the Evaluation of Carcinogenic Risks to Humans: Carbon Black, Titanium Dioxide, and Talc</i> 277 (2010).....	6, 15
Int'l Org. for Standardization, <i>Air Quality – Bulk Materials: Part 1: Sampling and Qualitative Determination of Asbestos in Commercial Bulk Materials</i> (2012).....	passim
Int'l Org. for Standardization, <i>Ambient Air – Determination of Asbestos Fibers – Indirect-Transfer Transmission Electron Microscopy Method</i> (1999).....	20, 29, 30, 36
Krewer & Millette, <i>Asbestos Analysis by Transmission Electron Microscopy In-House Training</i> , 38 <i>The Microscope</i> 97 (1990) .....	22, 37
Lowers & Meeker, <i>Tabulation of Asbestos-Related Terminology</i> (USGS, 2002) .....	7
Newbury & Ritchie, <i>Performing Elemental Microanalysis with High Accuracy and High Precision by Scanning Electron Microscopy</i> , 50 <i>J. Mater. Sci</i> 493 (2015) .....	36
Reid et al., <i>Does Exposure to Asbestos Cause Ovarian Cancer? A Systematic Literature Review and Meta-Analysis</i> , 20(7) <i>Cancer Epidemiol. Biomarkers &amp; Prev.</i> 1287 (2011).....	44, 47
U.S. Env'tl. Protection Agency, <i>Response to the November 2005 National Stone, Sand &amp; Gravel Association Report Prepared by the R.J. Lee Group, Inc. "Evaluation of EPA's Analytical Data from the El Dorado Hills Asbestos Evaluation Project"</i> (Apr. 20, 2006).....	8
U.S. Geological Survey, <i>Some Facts About Asbestos</i> 2 (2001) .....	7

Yamate et al.,

*Methodology for the Measurement of Airborne Asbestos by Electron*

*Microscopy* 44 (1984)..... 31, 36

## **INTRODUCTION**

As plaintiffs' opposition brief confirms, plaintiffs' experts' opinions that Johnson's Baby Powder and Shower To Shower (the "Products") contain asbestos that causes ovarian cancer are based on numerous leaps of logic that defy scientific knowledge and methods. Science does not equate asbestos and cleavage fragments; but Drs. Longo and Rigler do. Science requires rigorous adherence to microscopy methods to identify asbestos; Drs. Longo and Rigler do not. Science has not established a causal relationship between environmental asbestos exposure and ovarian cancer, but plaintiffs' experts are not bothered by that. And science has not demonstrated that the relevant talc deposits contain asbestos; yet, Drs. Cook and Krekeler say they do anyway. These opinions each represent paradigmatic departures from reliable methods, mandating their exclusion under *Daubert*.

***First***, plaintiffs' opposition effectively reaffirms that Drs. Longo and Rigler used an unreliable methodology that counts nonasbestiform cleavage fragments as asbestos, and that their opinions do not fit the facts of this litigation for that reason. Plaintiffs' defense of the Longo-Rigler definition of "asbestos" (which includes cleavage fragments) misrepresents the regulatory materials they cite, which universally exclude cleavage fragments from the definition of asbestos. Plaintiffs likewise fail to refute that their own causation experts exclude cleavage fragments from the definition of asbestos, since these experts both rely on definitions that

exclude cleavage fragments and do not contend or offer any scientific evidence that cleavage fragments can cause ovarian cancer.

*Second*, plaintiffs are unable to defend the numerous ways in which Drs. Longo and Rigler employed unreliable microscopy methodologies, including their repeated deviation from the protocols they claimed to follow and their reliance on subjective and error-prone judgment calls. Rather than show that these techniques are valid, plaintiffs rely almost exclusively on Dr. Longo's own assurance that they are reliable, which is plainly insufficient under *Daubert*.

*Third*, even assuming, arguendo, that Drs. Longo and Rigler had reliably identified small amounts of asbestos in the Products, plaintiffs' reply confirms that they have zero evidence that the amount and type of asbestos alleged to be present in the Products could ever cause ovarian cancer. Indeed, they fail to dispute that 50-year exposures to the amounts of asbestos allegedly found by Drs. Longo and Rigler would be *thousands of times lower* than exposure levels considered safe by the Occupational Safety and Health Administration ("OSHA") and the relevant scientific literature. Plaintiffs' attempt to sidestep this evidentiary void by recasting Drs. Longo and Rigler's claimed findings as relevant to biological plausibility also fails and confirms that plaintiffs are pursuing an "any exposure" theory of causation that lacks scientific support and that courts have repeatedly condemned as unreliable.

*Fourth*, plaintiffs also cannot refute that the opinions of Drs. Cook and Krekeler do not rest on reliable methods or data. Plaintiffs admit that Drs. Cook and Krekeler's opinions are based on identical charts that were created by plaintiffs' counsel, and while they assert that Drs. Cook and Krekeler helped create the charts, that assertion lacks support. Plaintiffs also do not dispute that Drs. Cook and Krekeler rely on many materials that have nothing to do with the Products or do not identify the asbestiform varieties of the minerals at issue in the documents. While plaintiffs brush aside these methodological flaws as "errors" that ostensibly go to credibility, these arguments are entirely untenable in light of the experts' extensive reliance on these inapposite materials. Finally, plaintiffs' effort to recharacterize Dr. Krekeler's testimony on the health effects of cleavage fragments to avoid the fact that he is not qualified to testify on health issues is absurd and should be rejected.

For all of these reasons, and those set forth in defendants' opening brief ("Defs.' Br."), the Court should exclude plaintiffs' experts' asbestos-related opinions.

## **ARGUMENT**

### **I. DRS. LONGO AND RIGLER’S OPINIONS SHOULD BE EXCLUDED BECAUSE THEY REDEFINE “ASBESTOS” FOR LITIGATION PURPOSES.**

Plaintiffs concede that the methodology employed by Drs. Longo and Rigler counts cleavage fragments as asbestos.<sup>1</sup> This alone renders their opinions inadmissible because, as set forth in defendants’ opening brief: (1) cleavage fragments are not asbestos; and (2) cleavage fragments are not understood to have the harmful health effects of asbestos – indeed, none of plaintiffs’ experts contends that exposure to cleavage fragments causes ovarian cancer.<sup>2</sup> Accordingly, Drs. Longo and Rigler’s definition of “asbestos” – which includes cleavage fragments – does not “fit” the facts of this litigation. Plaintiffs’ arguments in response are meritless.

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<sup>1</sup> (See Pls.’ Steering Committee’s Mem. in Resp. & Opp’n to Johnson & Johnson and Johnson & Johnson Consumer Inc.’s Mot. to Exclude Pls.’ Experts’ Asbestos-Related Ops. (“Pls.’ Opp’n”) at 35-49, May 29, 2019 (ECF No. 9892).) Dr. Longo likewise concedes that if he saw a nonasbestiform cleavage fragment, he “would count it and report it in [his] reports as asbestos.” (Trial Tr. 149:18-20, *Rimondi v. BASF Catalysts LLC*, No. MID-L-2912-17 (N.J. Super. Ct. Law Div. Mar. 5, 2019) (“Longo *Rimondi* Tr. Vol. I”) (attached as Ex. E29 to Certification of Julie L. Tersigni (“Tersigni Cert.”), May 7, 2019 (ECF No. 9723-2))).)

<sup>2</sup> A detailed discussion about the health effects of cleavage fragments can be found in defendants’ opening brief. (See Defs.’ Mem. of Law in Supp. of Mot. to Exclude Pls.’ Experts Asbestos-Related Ops. (“Defs.’ Br.”) at 10-12, 105-109, May 7, 2019 (ECF No. 9736-3).)

**A. Plaintiffs Misrepresent Health And Regulatory Bodies’ Definitions Of Asbestos In Attempting To Defend Dr. Longo’s Litigation Definition.**

Every health and regulatory authority defines asbestos as the *asbestiform* version of six regulated minerals, distinguishing asbestos from cleavage fragments.<sup>3</sup> Plaintiffs argue that there are actually “several definitions of asbestos that differ based on the use and context,” that defendants’ definition involves only “[c]ommercial viability,” not “health hazard[s],”<sup>4</sup> and that health and regulatory authorities reject the distinction between asbestos fibers and cleavage fragments.<sup>5</sup> Plaintiffs further argue that the “counting rules” Drs. Longo and Rigler used are the universally accepted way to positively identify asbestos.<sup>6</sup> None of this is correct.

*First*, plaintiffs’ argument that health and regulatory authorities do not distinguish between asbestos and cleavage fragments is frivolous. Here is how these authorities define asbestos:

- **IARC:** “[W]hen asbestiform, [six minerals] constitute asbestos, and, when not asbestiform, they are referred to as mineral fragments or cleavage

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<sup>3</sup> (Defs.’ Br. at 5-12, 26.)

<sup>4</sup> (Pls.’ Opp’n at 35-37, 44.)

<sup>5</sup> (*Id.* at 40-42.)

<sup>6</sup> (*Id.* at 43-44.)

fragments.”<sup>7</sup>

- **EPA:** “Asbestos means the *asbestiform* varieties of: chrysotile (serpentine); crocidolite (riebeckite); amosite (cummingtonite-grunerite); tremolite; anthophyllite; and actinolite.” 40 C.F.R. § 763.163 (emphasis added); 40 C.F.R. § 61.141 (same).
- **MSHA:** “Asbestos is a generic term for a number of *asbestiform* hydrated silicates that, when crushed or processed, separate into flexible fibers made up of fibrils.” 30 C.F.R. § 71.702(a) (emphasis added). It “does not include nonfibrous or nonasbestiform minerals.” 30 C.F.R. Parts 56, 57, and 71 Asbestos Exposure Limit; Final Rule, 73 Fed. Reg. 11,284, 11,292 (MSHA Feb. 29, 2008) (citation omitted).
- **OSHA:** “Asbestos includes chrysotile, amosite, crocidolite, tremolite *asbestos*, anthophyllite *asbestos*, [and] actinolite *asbestos* . . . .” 29 C.F.R. § 1910.1001(b) (emphases added). This definition “remove[s] nonasbestiform tremolite, anthophyllite, and actinolite from [its] scope.” Occupational Exposure to Asbestos, Tremolite, Anthophyllite and Actinolite, 57 Fed. Reg. 24,310, 24,310 (OSHA June 8, 1992).

Nobody would contend that these are not health-focused organizations.<sup>8</sup> And as the definitions set forth above make clear, these organizations distinguish between asbestos and nonasbestiform versions of the relevant minerals (or cleavage fragments). Thus, plaintiffs are simply wrong that “the agencies that regulate

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<sup>7</sup> Int’l Agency for Research on Cancer, World Health Org., 93 *Monographs on the Evaluation of Carcinogenic Risks to Humans: Carbon Black, Titanium Dioxide, and Talc* 277 (2010) (“IARC 2010 Monograph”) (attached as Ex. A72 to Tersigni Cert.).

<sup>8</sup> (E.g., Pls.’ Opp’n at 35 (conceding that OSHA, MSHA and the EPA define asbestos “for health and regulatory purposes”).)



asbestos have rejected the false distinction between ‘asbestos’ and cleavage fragments.”<sup>9</sup>

Plaintiffs misleadingly cite two sources out of context to support their contrary view. The first is a general statement by the United States Geological Survey (“USGS”) that asbestos terminology “can vary depending on the source and purpose.”<sup>10</sup> But plaintiffs ignore that the USGS has stated that **“when it comes to health risk,” it “matter[s] whether an amphibole is asbestiform.”**<sup>11</sup>

This is because “available evidence supports a conclusion that exposure to nonasbestiform cleavage fragments is not likely to produce a significant risk of developing asbestos-related disease.”<sup>12</sup> Accordingly, the relevant USGS definition accepts, rather than rejects, the distinction between asbestos and cleavage fragments.

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<sup>9</sup> (Pls.’ Opp’n at 41.)

<sup>10</sup> (*Id.* at 35-36 (citing Lowers & Meeker, *Tabulation of Asbestos-Related Terminology* (USGS, 2002)).)

<sup>11</sup> U.S. Geological Survey, *Some Facts About Asbestos* 2 (2001) (quoting 57 Fed. Reg. 24,310) (attached as Ex. A146 to Tersigni Cert.).

<sup>12</sup> *Id.* Defendants agree that this litigation is not about whether an asbestos deposit has other characteristics – like the “location, amount, and extractability of the deposit” – to make it commercially viable for mining. (*E.g.*, Pls.’ Opp’n at 37.) Defendants have never pressed such a definition.

Plaintiffs also claim that the Environmental Protection Agency (“EPA”) does not distinguish between asbestos and cleavage fragments.<sup>13</sup> This, too, is impossible to square with the EPA’s definition of asbestos, which encompasses only *asbestiform* minerals. 40 C.F.R. § 763.163; 40 C.F.R. § 61.141 (“[a]sbestos means the *asbestiform* varieties of” six minerals) (emphasis added). While plaintiffs cite a report from a single regional office of the EPA (“Region IX”) that supposedly supports their position, this is not a statement from the EPA as an institution and does not supersede the definition codified in the Code of Federal Regulations – which, as explained above, *does not* count cleavage fragments as asbestos. Moreover, contrary to plaintiffs’ portrayal, the Region IX report does not actually conclude that asbestos and cleavage fragments are synonymous. Instead, it recommends erring on the side of caution because, in Region IX’s view, it lacked sufficient evidence to prove that cleavage fragments were safe.<sup>14</sup> This is far from a determination that cleavage fragments are unsafe, much less that they are just as harmful as asbestos – a position regulatory agencies have actually rejected. *See, e.g.,* 57 Fed. Reg. at 24,310 (OSHA’s determination “that substantial evidence is

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<sup>13</sup> (Pls.’ Opp’n at 41-42.)

<sup>14</sup> (*Id.* (quoting U.S. Env’tl. Protection Agency, *Response to the November 2005 National Stone, Sand & Gravel Association Report Prepared by the R.J. Lee Group, Inc. “Evaluation of EPA’s Analytical Data from the El Dorado Hills Asbestos Evaluation Project,”* at 2-3 (Apr. 20, 2006)).)

lacking to conclude that nonasbestiform [minerals] present the same type or magnitude of health effect as asbestos”).

In short, the precautionary approach taken in a lone report by a district office does not supersede the EPA’s actual definition of asbestos and does not provide a scientific basis for counting cleavage fragments as asbestos. *See, e.g., Glastetter v. Novartis Pharm. Corp.*, 252 F.3d 986, 991 (8th Cir. 2001) (per curiam) (regulatory agencies “us[e] a different standard than the causation standard” in a tort case, as their “preventive perspective” warrants acting “upon a lesser showing of harm”) (citations omitted); *Rider v. Sandoz Pharm. Corp.*, 295 F.3d 1194, 1201 (11th Cir. 2002) (“A regulatory agency such as the FDA may choose to err on the side of caution. Courts, however, are required by the *Daubert* trilogy to engage in objective review of evidence to determine whether it has sufficient scientific basis to be considered reliable.”); *In re Zicam Cold Remedy Mktg., Sales Practices, & Prods. Liab. Litig.*, No. 09-md-2096-PHX-FJM, 2011 WL 798898, at \*10-11 (D. Ariz. Feb. 24, 2011) (excluding expert’s reliance on “prevention-oriented” FDA materials under *Daubert*).<sup>15</sup>

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<sup>15</sup> Plaintiffs’ argument regarding high tensile strength and flexibility is a red herring. (*See* Pls.’ Opp’n at 38-40.) Even Dr. Longo agrees that these are definitional attributes of asbestos. (2d Suppl. Expert Report of William E. Longo, Ph.D. & Mark W. Rigler, Ph.D. (“2d Suppl. Longo Rep.”) at 24, Feb. 1, 2019 (attached as Ex. C1 to Tersigni Cert.)). Moreover, defendants have never argued that these attributes must be tested to determine if a particle is asbestos. Rather,

**Second**, plaintiffs’ argument that “[r]egulators and J&J” use “counting criteria [to] determine what ‘counts’ as an asbestos fiber”<sup>16</sup> is wrong, because like Drs. Longo and Rigler, they mistakenly equate “counting criteria” with the definition of “asbestos.” The former only identifies “fibers,” not necessarily *asbestos* fibers.<sup>17</sup> To be an *asbestos fiber*, a fiber must also be asbestiform, as Dr. Longo has acknowledged.<sup>18</sup> The counting rules must be considered in context, because they are designed to determine how much asbestos there is after it has already been identified – not to positively identify it in the first instance. This is why the counting rules do not themselves define asbestos – the regulations do that elsewhere. Plaintiffs do not even attempt to address this issue, and instead

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the attributes that *can* be tested for – such as “splayed ends,” “curvature” and the aspect ratio distribution of a population of particles – are *evidence* of high tensile strength and flexibility. Int’l Org. for Standardization, *Air Quality – Bulk Materials: Part 1: Sampling and Qualitative Determination of Asbestos in Commercial Bulk Materials* 22-23 (2012) (“ISO 22262-1”) (attached as Ex. A74 to Tersigni Cert.) (protocol purportedly followed by Drs. Longo and Rigler stating that “the asbestiform habit is generally recognized” by these attributes).

<sup>16</sup> (Pls.’ Opp’n at 43-44 (emphasis omitted).)

<sup>17</sup> Tellingly, plaintiffs discuss provisions in OSHA, MSHA and EPA regulations setting forth counting rules, but do not actually cite these regulations. (See *id.* at 43.) As explained above, the regulations themselves make clear that fibers must be asbestiform to be asbestos.

<sup>18</sup> (See Defs.’ Br. at 40 n.101 (quoting Dr. Longo: “[T]here’s no way to tell with just TEM, if you’re looking at a single fiber, if it’s asbestiform or not”) (citing Dep. of William E. Longo, Ph.D. (“Longo Anderson Dep.”), *Anderson v. Borg-Warner Corp.*, No. JCCP 5674/BC666513 (Cal. Super. Ct. Mar. 29, 2018)) (supplemental excerpt attached as Ex. E35 to 2d Suppl. Certification of Julie L. Tersigni (“2d Suppl. Tersigni Cert.”))).

implicitly concede it in acknowledging that particles that satisfy the counting criteria must be “confirm[ed] [to be asbestos] through analysis of crystal structure and elemental chemistry.”<sup>19</sup>

*Finally*, plaintiffs imply that Drs. Longo and Rigler’s definition of asbestos does not matter because the particles they identified have certain characteristics that made it reasonable for Dr. Longo “to conclude that what he found . . . is, in fact, amphibole asbestos and not non-asbestiform chunks.”<sup>20</sup> Specifically, plaintiffs point to Drs. Longo and Rigler’s claimed identification of (1) “bundles”; (2) a population of particles with an average aspect ratio greater than 5:1; and (3)

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<sup>19</sup> (Pls.’ Opp’n at 43-44.) Plaintiffs misrepresent defendants’ internal documents in claiming that defendants themselves have “define[d] an ‘asbestiform mineral’ as ‘An elongated particle with parallel sides and an aspect ratio  $\geq$  3:1.’” (*Id.* at 44 (quoting JNJMX68\_000018545); *see also id.* at 48 (repeating claim).) Plaintiffs’ quotation is to the definition of a *fiber*, not the definition of an “asbestiform mineral.” (See JNJNL61\_000005038 (attached as part of Ex. 94 to Pls.’ Opp’n) (“Definition of *fiber*: An elongated particle with parallel sides and an aspect ratio K3:1.”) (emphasis added.); JNJTALC000008863 (attached as Ex. 95 to Pls.’ Opp’n) (same); JNJTALC000008856 (attached as Ex. 96 to Pls.’ Opp’n) (same).) Plaintiffs similarly misrepresent internal testing documents that they claim are positive for asbestos. For example, plaintiffs cite to a *draft* report from McCrone labs as finding asbestos in defendants’ Vermont talc; in the final report, the lab states that it did *not* find any asbestiform materials. (See Pls.’ Br. at 16 n.48 (citing J&J 257); *see also* JNJAZ55\_000008893 (attached as Ex. D9 to 2d Suppl. Tersigni Cert.) (final report showing no asbestos).) And plaintiffs cite J&J-182, which is a sample from a California mine plaintiffs do not even allege is a source for the Products. (Pls.’ Opp’n at 16 n.49 (citing J&J-182 (attached as Ex. 49 to Pls.’ Opp’n)).)

<sup>20</sup> (Pls.’ Opp’n at 44-49.)

the presence of some particles with aspect ratios greater than 20:1.<sup>21</sup> As explained below, this argument is scientifically incorrect because Drs. Longo and Rigler do not reliably identify “bundles,” and the alleged population and aspect ratio characteristics do not dictate that the particles are asbestos.<sup>22</sup> But plaintiffs’ argument should be rejected at the outset because Drs. Longo and Rigler did not opine in their reports that these characteristics make it likely that the particles they identified are asbestos.<sup>23</sup> And plaintiffs’ attempt to save Drs. Longo and Rigler’s opinions on grounds that the experts themselves did not reference fails as a matter of law. *See, e.g., B.H. ex rel. Holder v. Gold Fields Mining Corp.*, No. 04-CV-0564-CVE-PJC, 2007 WL 188130, at \*3 (N.D. Okla. Jan. 22, 2007) (rejecting “plaintiffs’ attempt to create an after-the-fact justification” for an incorrect calculation by describing various adjustments the expert could have made to the

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<sup>21</sup> (*Id.*)

<sup>22</sup> (*See* § II.A, *infra.*)

<sup>23</sup> Rather, Drs. Longo and Rigler report every particle larger than 5 micrometers with an aspect ratio greater than or equal to 5:1 as asbestos – regardless of whether the population has an average aspect ratio greater than 5:1 or there are particles with aspect ratios greater than 20:1, and regardless of whether the particle is identified as a “fiber” or a “bundle.” (Defs.’ Br. at 17-18, 26-27 (citing, *inter alia*, 2d Suppl. Longo Rep. at 12); Pls.’ Opp’n at 44 (quoting Dep. of William E. Longo, Ph.D. (“Longo Dep.”) 238:13-19, 239:2-22, Feb. 5, 2019 (attached as Ex. B48 to Tersigni Cert.)).) Indeed, Dr. Longo has admitted that the result of this approach is that if he saw a nonasbestiform cleavage fragment, he “would count it and report it in [his] reports as asbestos.” (Longo *Rimondi* Tr. Vol. I 148:17-25.)

calculation to reach the correct result; “[e]ven if [the expert] reached [the expected] result . . . this does not prove that [his] *methodology* was reliable”) (emphasis added); *see also Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 595 (1993) (explaining that the focus of the inquiry is on the expert’s methods rather than conclusions).<sup>24</sup> Accordingly, even if plaintiffs’ after-the-fact justifications were correct, they would not make Drs. Longo and Rigler’s opinions admissible.

In sum, there is a universal regulatory definition of asbestos that excludes nonasbestiform cleavage fragments, and plaintiffs cannot deny that Drs. Longo and Rigler ignore it. Accordingly, their approach of concluding that every particle that satisfies the counting rules is ““regulated asbestos””<sup>25</sup> is unreliable and alone requires exclusion of their opinions – irrespective of the justifications provided for the first time in plaintiffs’ opposition brief.

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<sup>24</sup> *See also Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 672-73 (6th Cir. 2010) (rejecting counsel’s effort to redefine the expert’s opinion; the expert’s “opinion cannot escape its own logic”); *Nilssen v. Motorola, Inc.*, No. 93 C 6333, 1998 WL 851493, at \*2 (N.D. Ill. Dec. 1, 1998) (citing Fed. R. Civ. P. 26(a)(2)(B)) (party’s “attempt[] to save” an expert’s calculation “by arguing that [the expert] considered [certain relevant] factors” was rejected as “a post-hoc rationalization” because the expert never identified those factors as bearing on this calculation); *Caraker v. Sandoz Pharm. Corp.*, 172 F. Supp. 2d 1046, 1049 & n.5 (S.D. Ill. 2001) (excluding testimony of an expert who used a flawed methodology and then, as “an afterthought,” applied a different methodology to reach the same conclusion because “[j]ustifying a conclusion after the fact by applying a methodology does not generally lead to reliable scientific knowledge”).

<sup>25</sup> (Pls.’ Opp’n at 44 (citing Longo Dep. 239:2-22).)



**B. Drs. Longo And Rigler’s Definition Of Asbestos Is Inapposite Because It Is Different From That Of Plaintiffs’ Causation Experts.**

Plaintiffs’ opposition fails to even address, let alone contest, an independent dispositive issue: Drs. Longo and Rigler’s definition of “asbestos,” whatever its merits, is not the definition used by plaintiffs’ causation experts.<sup>26</sup> Specifically,

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<sup>26</sup> Plaintiffs’ causation and biological plausibility experts – Drs. Carson, Clarke-Pearson, Kane, Levy, McTiernan, Moorman, Plunkett, Siemiatycki, Singh, Smith, Smith-Bindman, Wolf and Zelikoff – generally contend that asbestos causes ovarian cancer or that the alleged presence of asbestos in the Products provides a biologically plausible mechanism by which talc use can cause ovarian cancer. (*See, e.g.*, Expert Report of Judith Zelikoff, Ph.D. (“Zelikoff Rep.”) at 4-5, Nov. 16, 2018 (attached as Ex. C24 to Tersigni Cert.); Expert Report of Expert Report of Shawn Levy, Ph.D. (“Levy Rep.”) at 13, 15-16, Nov. 16, 2018 (attached as Ex. C39 to Tersigni Cert.); Expert Report of Judith Wolf, M.D. at 9, Nov. 16, 2018 (attached as Ex. C23 to Tersigni Cert.); Expert Report of Rebecca Smith-Bindman, M.D. at 14-15, Nov. 15, 2018 (attached as Ex. C36 to Tersigni Cert.); Expert Report of Sarah E. Kane, M.D. at 5, 29, Nov. 15, 2018 (attached as Ex. C38 to Tersigni Cert.); Expert Report of Anne McTiernan, M.D., Ph.D. (“McTiernan Rep.”) at 8-9, 57, Nov. 16, 2018 (attached as Ex. C7 to Tersigni Cert.); Expert Report of Arch Carson, M.D., Ph.D. (“Carson Rep.”) at 5, Nov. 16, 2018 (attached as Ex. C9 to Tersigni Cert.); Expert Report of Daniel L. Clarke-Pearson, M.D. (“Clarke-Pearson Rep.”) at 5, Nov. 16, 2018 (attached as Ex. C14 to Tersigni Cert.); Expert Report of Ellen Blair Smith, M.D. (“Smith Rep.”) at 18, Nov. 16, 2018 (attached as Ex. C16 to Tersigni Cert.); Expert Report of Jack Siemiatycki, M.Sc., Ph.D. (“Siemiatycki Rep.”) at 29-30, Nov. 16, 2018 (attached as Ex. C21 to Tersigni Cert.); Expert Report of Laura M. Plunkett, Ph.D., D.A.B.T. at 19, Nov. 16, 2018 (attached as Ex. C28 to Tersigni Cert.); Expert Report of Patricia G. Moorman, M.S.P.H., Ph.D. at 35, Nov. 16, 2018 (attached as Ex. C35 to Tersigni Cert.); Expert Report of Sonal Singh, M.D., M.P.H. (“Singh Rep.”) at 16, Nov. 16, 2018 (attached as Ex. C40 to Tersigni Cert.)) These experts rely nearly exclusively on Drs. Longo and Rigler’s opinions for the proposition that the Products contain asbestos. (*See, e.g.*, Smith Rep. at 18; Carson Rep. at 5; Clarke-Pearson Rep. at 6; Levy Rep. at 15; Zelikoff Rep. at 8; McTiernan Rep. at 57.) But



although Drs. Longo and Rigler count nonasbestiform cleavage fragments as asbestos, plaintiffs' other general causation experts rely on IARC's definition of asbestos – which differentiates between cleavage fragments and asbestos.<sup>27</sup> Thus, for example, none of the scientific literature on which plaintiffs' experts rely purports to link ovarian cancer and cleavage fragments.<sup>28</sup> As defendants explained in their opening brief, this mismatch between Drs. Longo and Rigler's definition and that of plaintiffs' causation experts renders Drs. Longo and Rigler's opinions inadmissible for lack of "fit."<sup>29</sup>

In their opposition, plaintiffs concede that Drs. Longo and Rigler use an entirely different definition of asbestos from plaintiffs' other experts.<sup>30</sup> Plaintiffs nevertheless attempt to justify Drs. Longo and Rigler's approach, claiming that

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none of them contends that the presence of nonasbestiform cleavage fragments supports causation.

<sup>27</sup> (Defs.' Br. at 35-37 (explaining that IARC distinguishes between asbestos and nonasbestiform cleavage fragments).) *See also* IARC 2010 Monograph at 277 (the six regulated minerals "when asbestiform . . . constitute asbestos and, when not asbestiform . . . are referred to as mineral fragments or cleavage fragments").

<sup>28</sup> (*See infra* at 61-64.)

<sup>29</sup> (Defs.' Br. at 35-37.)

<sup>30</sup> (*See, e.g.*, Pls.' Opp'n at 44 (citing Drs. Longo's deposition testimony conceding that he classifies all particles longer than 5 microns with an aspect ratio greater than or equal to 5:1 as asbestos without regard to whether they are asbestiform).)

cleavage fragments are just as harmful as asbestos.<sup>31</sup> But *not one* of plaintiffs' gynecologic oncologists, toxicologists or epidemiologists opines that cleavage fragments have the same harmful effects as asbestos.<sup>32</sup>

Because the overarching focus of the *Daubert* inquiry here is general causation, Longo and Rigler's purported findings of "asbestos" only matter to the extent that they are tied to general causation. The Longo-Rigler definition of asbestos is not. For this reason, too, Drs. Longo and Rigler's opinions should be excluded. *See, e.g., In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 743 (3d Cir. 1994); *Soldo v. Sandoz Pharm. Corp.*, 244 F. Supp. 2d 434, 548-50 (W.D. Pa. 2003).

## **II. PLAINTIFFS FAIL TO REFUTE THAT DRs. LONGO AND RIGLER'S MICROSCOPIC ANALYSIS WAS UNRELIABLE.**

Drs. Longo and Rigler's opinions are also inadmissible because their microscopy methodologies (TEM, SAED, EDXA and PLM) were unreliable. Specifically, Longo and Rigler failed to follow the protocols they purport to have relied on and generated unverifiable and inconsistent results.<sup>33</sup>

Plaintiffs' arguments in response lack merit.

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<sup>31</sup> (*See, e.g.,* Pls.' Opp'n at 41-42.)

<sup>32</sup> The only expert who even purports to opine on this topic is the geologist Dr. Krekeler. As defendants explained in their opening brief and elaborate below, such opinions are well beyond his field of expertise and wholly without foundation.

<sup>33</sup> (*See* Defs.' Br. at 37-80.)

As a threshold matter, plaintiffs repeatedly argue that these issues go to weight rather than admissibility, but that is incorrect because “*any* step that renders [an expert’s] analysis unreliable under the *Daubert* factors renders the expert’s testimony inadmissible.” *In re Zolof (Sertraline Hydrochloride) Prods. Liab. Litig.*, 858 F.3d 787, 797 (3d Cir. 2017) (citation omitted). Moreover, courts have a “gatekeeping obligation” to ensure that expert testimony “is not only relevant, but reliable,” *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 147 (1999) (citation omitted), and methodologies that are “fundamentally flawed” must be excluded, *Citizens Fin. Grp., Inc. v. Citizens Nat’l Bank of Evans City*, 383 F.3d 110, 121 (3d Cir. 2004) (rejecting weight argument where the underlying “methodology was fundamentally flawed”); *see also Zolof*, 858 F.3d at 792-93 (exclusion is necessary when “the flaw is large enough that the expert lacks the ‘good grounds’ for his or her conclusions”) (citation omitted). As explained in defendants’ opening brief and discussed further below, the problems with Drs. Longo and Rigler’s methodology are fundamental flaws that demand exclusion because they each contributed to these experts’ failure to reliably demonstrate that the Products contain asbestos, which is the “core” of their opinions. *See Bruno v. Bozzuto’s, Inc.*, 311 F.R.D. 124, 140 (M.D. Pa. 2015) (explaining that the common argument that methodological flaws go to weight fails when the “flaws go to the core body of the proffered evidence”).

Plaintiffs also offer a long, irrelevant description of the various sample preparation techniques used by Drs. Longo and Rigler and of the ISO protocols they purported to follow,<sup>34</sup> but this expansive discussion misses the point because Drs. Longo and Rigler did not actually follow the ISO protocols they invoke, and even generally-accepted methodologies must be “reliably applied.” *See Zoloff*, 858 F.3d at 792 (citation omitted). Accordingly, courts routinely exclude experts – including Dr. Longo – who have “failed to apply [their] own methodology reliably.” *Amorgianos v. Nat’l R.R. Passenger Corp.*, 303 F.3d 256, 268-69 (2d Cir. 2002); *In re Lamar Cty. Order* (excluding Dr. Longo because “the methodologies claimed to be used by MAS in the test reports were not followed”).<sup>35</sup>

When plaintiffs do finally address the methodological deficiencies laid out in defendants’ motion, they rely almost exclusively on Dr. Longo’s report and testimony to support their arguments.<sup>36</sup> In other words, the *only* source plaintiffs

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<sup>34</sup> (Pls.’ Opp’n at 49-62.)

<sup>35</sup> *See also, e.g., United States v. Tuzman*, No. 15 Cr. 536 (PGG), 2017 WL 6527261, at \*16-17 (S.D.N.Y. Dec. 18, 2017) (excluding expert who did not “provide[] any justification for [his] substantial deviations from the methodology he claims to have followed, other than his subjective belief that [the omitted steps were] unnecessary”); *Truck Ins. Exch. v. MagneTek, Inc.*, 360 F.3d 1206, 1213 (10th Cir. 2004); *Wessmann v. Gittens*, 160 F.3d 790, 805 (1st Cir. 1998); *Disabled in Action v. City of N.Y.*, 360 F. Supp. 3d 240, 244-47 (S.D.N.Y. 2019); *Eghnayem v. Bos. Sci. Corp.*, 57 F. Supp. 3d 658, 688 (S.D. W. Va. 2014). (See Defs.’ Br. at 28-29 & n.85.)

<sup>36</sup> (See, e.g., Pls.’ Opp’n at 63-82 (citing to Dr. Longo’s report or testimony more than **50 times**).) Plaintiffs cite to scientific sources only twice in this entire

could find to say that Drs. Longo and Rigler’s methodology is appropriate is Dr. Longo himself. That is plainly insufficient, since demonstrating reliability “requires some objective, independent validation of the expert’s methodology. The expert’s assurance[] that he has utilized generally accepted scientific methodology is insufficient.” *Moore v. Ashland Chem. Inc.*, 151 F.3d 269, 276 (5th Cir. 1998); *see also Fla. Power & Light Co. v. Qualified Contractors, Inc.*, No. 04-80505-Civ, 2005 WL 5955702, at \*4 (S.D. Fla. Dec. 6, 2005) (an argument that a methodology “should be considered reliable because [the expert] determined that it was reliable” is “illogical and circular at best”); *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1319 (9th Cir. 1995) (experts must “point to some objective source – a learned treatise, the policy statement of a professional association, a published article in a reputable scientific journal or the like – to show that they have followed the scientific method”).

For these reasons, discussed further below, plaintiffs’ efforts to defend Drs. Longo and Rigler’s TEM, SAED, EDXA and PLM analyses all fail.

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discussion, and both times to make concessions. (*See id.* at 69 nn.237-39 (conceding that the Yamate method requires multiple zone-axis diffraction patterns); *id.* at 77 (conceding that ISO 22262-1 “notes the limitations of PLM in the detection of asbestos”).)

**A. Plaintiffs Fail To Show That Drs. Longo And Rigler’s Visual TEM Analysis Was Reliable.**

As explained in defendants’ opening brief, Drs. Longo and Rigler claim to have predominantly identified asbestos “bundles” using TEM to escape their concession that visual TEM cannot determine whether an individual fiber is asbestiform or not – a point plaintiffs do not challenge.<sup>37</sup> But their purported detection of “bundles” was subjective and error-prone, and plaintiffs’ arguments fail to show otherwise.

Plaintiffs begin by contending that whether Drs. Longo and Rigler reliably identified bundles is “an eye-of-the-beholder argument.”<sup>38</sup> That is an indictment of their “methodology,” not a defense of it, however, because it essentially concedes that their bundle identification relies on nothing more than Dr. Longo’s subjective say-so. The only objective characteristic that plaintiffs mention, and only in passing, is “splayed ends”<sup>39</sup> – but Dr. Longo has (contrary to ISO 22262-1) *denied* that splayed ends are a characteristic of tremolite asbestos. This statement was presumably forced by the fact that, as he conceded, *none of the particles he*

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<sup>37</sup> (Defs.’ Br. at 40 (emphasis added).) *See also* Int’l Org. for Standardization, *Ambient Air – Determination of Asbestos Fibers – Indirect-Transfer Transmission Electron Microscopy Method 1* (1999) (“ISO 13794”) (attached as Ex. A166 to Suppl. Certification of Julie L. Tersigni (“Suppl. Tersigni Cert.”), May 29, 2019 (ECF No. 9867)).

<sup>38</sup> (Pls.’ Opp’n at 63.)

<sup>39</sup> (*Id.* at 64.)

*identified has splayed ends.*<sup>40</sup> In sum, no objective criteria support Drs. Longo and Rigler’s bundle classifications.

Unsurprisingly given the lack of objective criteria, there is staggering inconsistency among the MAS analysts’ purported identification of “bundles.” Plaintiffs’ only explanation is that the internal quality control test Dr. Longo conducted was designed to test whether the analysts identified the same structures, not whether they identified them consistently as bundles or fibers.<sup>41</sup> At the end of the day, the motivation for Dr. Longo’s quality control exercise is irrelevant – there was an extremely high error rate, and plaintiffs do not dispute it. This lack of reproducibility requires exclusion. *See, e.g., In re TMI Litig. Cases Consol. II*, 911

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<sup>40</sup> (See Dep. of William E. Longo, Ph.D. 105:6-108:17, *Rimondi v. BASF Catalysts LLC*, No. MID-L-2912-17 (N.J. Super. Ct. Law Div. Jan. 7, 2019) (“Longo *Rimondi* Dep.”) (supplemental excerpt attached as Ex. E36 to 2d Suppl. Tersigni Cert.)). Dr. Longo said of the particles he identified: “I don’t think there’s any splayed ends. There may be one or two.” (*Id.* 105:9-10.) When asked whether he had “a specific recollection of one or two [particles] displaying bundles with splayed ends,” he responded in the negative. (*Id.* 107:8-12.) When he was pressed further on this issue, he stated: “I wouldn’t expect to see splayed ends on any [of the particles he identified] . . . . [S]played ends is not a characteristic, in my opinion, of either tremolite or anthophyllite on these accessory minerals.” (*Id.* 108:13-17.) The contrary testimony that plaintiffs cite (*see* Pls.’ Br. at 64 n.212 (quoting Longo *Leavitt* Dep. 160:6-21)), is nothing more than Dr. Longo reading from ISO 22262-1 – which, per his deposition testimony in *Rimondi*, he apparently disagrees with.

<sup>41</sup> (Pls.’ Opp’n at 65-66.) Plaintiffs do not even attempt to defend Dr. Rigler’s nonsensical testimony that despite coming to *different determinations* as to whether a particle was a bundle or a fiber, the analysts “all got it right.” (Dep. of Mark W. Rigler, Ph.D. (“Rigler Dep.”) 184:20-24, Feb. 6, 2019 (attached as Ex. B35 to Tersigni Cert.)).

F. Supp. 775, 795-96 (M.D. Pa. 1996) (excluding expert because, among other things, his subjective techniques “expose[d] [the expert’s] methodology to a potentially high rate of error”); *Kim v. Crocs, Inc.*, No. 16-00460 JAO-KJM, 2019 WL 923879, at \*8 (D. Haw. Feb. 25, 2019) (“[I]t is unclear how sound and reliable opinions could be corroborated by data that [the expert] himself admits had a high rate of error.”); *Ruffin v. Shaw Indus., Inc.*, 149 F.3d 294, 297-98 (4th Cir. 1998) (per curiam) (“[A] ‘key question’” under *Daubert* is “whether [a methodology] has been tested and independently validated or replicated.”).<sup>42</sup>

Plaintiffs’ other attempted defenses of Drs. Longo and Rigler’s results are incorrect and should be disregarded because they are post hoc justifications that were not disclosed, as explained above. *See, e.g., Gold Fields Mining*, 2007 WL 188130, at \*3 (rejecting “plaintiffs’ attempt to create an after-the-fact justification” for the expert’s calculation). For example, plaintiffs provide pictures that, in their view, are “clearly” of bundles.<sup>43</sup> Yet, these pictures are nowhere to be found in the Longo-Rigler reports. Instead, they are images from a report in a different case that were taken with a type of microscope that Drs. Longo and Rigler did not even

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<sup>42</sup> *See also, e.g.,* Krewer & Millette, *Asbestos Analysis by Transmission Electron Microscopy In-House Training*, 38 *The Microscope* 97, 107 (1990) (“Krewer 1990”) (attached as Ex. A168 to Suppl. Tersigni Cert.) (“If any evidence of misidentification or counting problems are revealed by the quality system checks, then the source of this must be located and corrected, of course.”).

<sup>43</sup> (Pls.’ Opp’n at 46.)

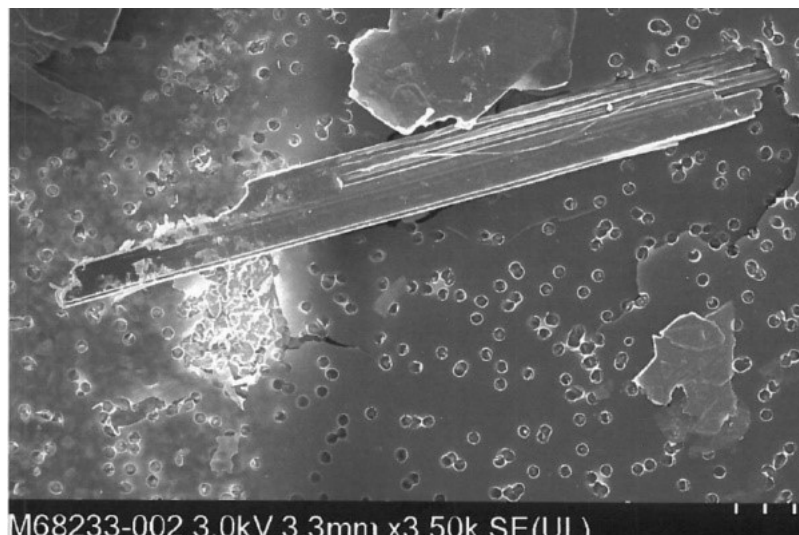


use here.<sup>44</sup> In any event, it is not at all “clear[]” that these images are bundles of fibers as opposed to extremely zoomed-in images of a single cleavage fragment. This is especially true because plaintiffs included only a *partial image* of the particle in question in their brief. The full image, depicted on the next page, has a jagged, broken-off left end that is paradigmatic of cleavage fragments, not asbestos bundles:<sup>45</sup>

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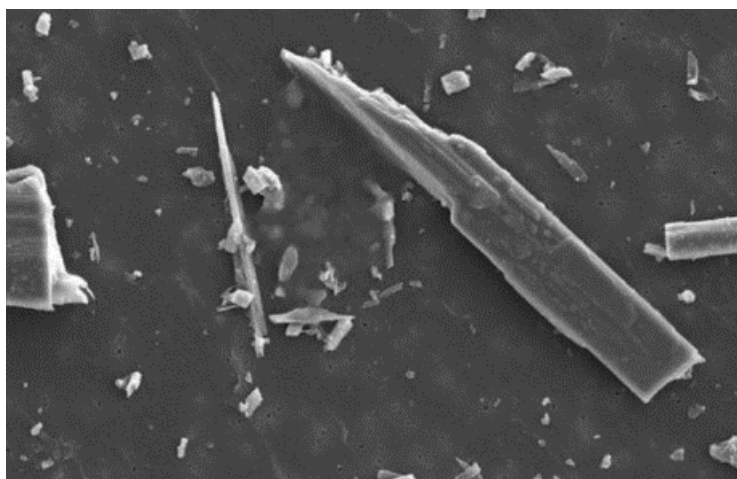
<sup>44</sup> (See *id.* at 47 n.157 (citing SEM Photomicrographs of 1978 JJ Museum Sample along with Presentation by RJ Lee Regarding Asbestiform v. Non-Asbestiform for Comparison).) These images were taken with a scanning electron microscope (“SEM”). Plaintiffs do not provide a citation for these images and instead misleadingly cite to page 723 of Drs. Longo and Rigler’s January 15, 2019 supplemental report in footnote 156, right above the images. But the SEM images are nowhere to be found on page 723 of that report. (See Longo & Rigler, Supplemental Report: The Analysis of Johnson & Johnson’s Historical Product Containers and Imerys’ Historical Railroad Car Samples from the 1960’s to the Early 2000’s for Amphibole Asbestos, at 723, Jan. 15, 2019 (attached as Ex. C42 to 2d Suppl. Tersigni Cert.).)

<sup>45</sup> Cleavage fragments derive their name from the fact that the particles break, or cleave, along the natural grain in the mineral. See 73 Fed. Reg. at 11,285. The horizontal lines toward the top right of the particle illustrate fracture along these grains rather than the bundling of individual fibers.



**Figure \_:** Full Image of Particle from Plaintiffs' Exhibit 98 (at 3)

Comparing this image to a textbook cleavage fragment image from the USGS provides further confirmation that it is not a bundle:<sup>46</sup>



**Figure \_:** SEM image of nonasbestiform tremolite cleavage fragments

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<sup>46</sup> U.S. Geological Survey, Tremolite Image Nos. 18, 20 (attached as Ex. A147 to Tersigni Cert., at 4).

In short, plaintiffs' use of a partial image taken from a different microscope in a different case only serves to underscore the unscientific and misleading nature of Drs. Longo and Rigler's methodology.

Plaintiffs also argue that the samples Drs. Longo and Rigler tested likely contained asbestos because their particles had high average aspect ratios and there were some particles with aspect ratios greater than 20:1.<sup>47</sup> This is wrong for several reasons. For starters, the notion that the particles Drs. Longo and Rigler identified were asbestiform because there was "an average aspect ratio higher than 5:1" ignores that Drs. Longo and Rigler *only counted* structures with aspect ratios greater than or equal to 5:1.<sup>48</sup> Excluding smaller particles skewed the results, and a calculation of the "average" that omits such particles says nothing about what the average particle size really was. In fact, as Dr. Dyar explains in her report, the overall sizes of the particles Drs. Longo and Rigler identified more closely match the typical sizes of cleavage fragments than asbestos – even when all particles with aspect ratios lower than 5:1 are excluded.<sup>49</sup> Moreover, the "Aspect Ratio

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<sup>47</sup> (Pls.' Opp'n at 47-48 (arguing both that "the presence of any single bundle or fiber longer than 20 microns in a sample, or a sample with fibers/bundles with an average aspect ratio higher than 5:1 supports the conclusion that the sample reviewed is asbestiform").)

<sup>48</sup> (See Pls.' Opp'n at 48.)

<sup>49</sup> (See Expert Report of M. Darby Dyar, Ph.D. ("Dyar Rep.") at 61-66, Feb. 25, 2019 (attached as Ex. C30 to Tersigni Cert.) (providing charts comparing the incomplete Longo/Rigler size distribution data to that of asbestiform and

Distribution” chart that plaintiffs include on page 49 of their brief that supposedly shows that the aspect ratios of the particles they detected are consistent with asbestos is inapposite because the data in the chart are not from bottles Drs. Longo and Rigler tested for the MDL proceeding.<sup>50</sup>

Finally, the presence of some structures with aspect ratios greater than 20:1 does not mean that a sample contains asbestiform fibers.<sup>51</sup> Indeed, Dr. Longo acknowledges that nonasbestiform minerals can “break in all sorts of different shapes and sizes” and that some pieces “may be long and thin,” “resembl[ing] asbestos fibers.”<sup>52</sup> A contrary approach would consider any structure with a greater than 20:1 aspect ratio an asbestos fiber or bundle, including, for example, a chunk of tremolite rock one foot wide and twenty feet long. For this reason, the section of the ISO protocol that plaintiffs cite merely articulates the common-sense

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nonasbestiform particles, showing that Longo and Rigler’s data more closely correspond to the latter).)

<sup>50</sup> (Compare Pls.’ Opp’n at 49 (chart plotting 304 particles) *with* 2d Suppl. Longo Rep. at 34-48 (identifying 157 total particles).) Rather, the chart depicts data from bottles Drs. Longo and Rigler purchased through eBay in other litigation. These bottles are plagued with chain-of-custody problems that raise questions about contamination, and opinions based on these bottles have been excluded on these grounds in other cases, which is presumably why they are not included in the Longo-Rigler MDL reports. (See Pls.’ Opp’n at 30; Rulings on Mots. in Lim., Ex. B at 27-41, *Weirick v. Brenntag N. Am., Inc.*, No. BC656425 (Cal. Super. Ct. July 23, 2018) (attached as Ex. E16 to Tersigni Cert.).)

<sup>51</sup> (See Pls.’ Opp’n at 48 (citing ISO 22262).)

<sup>52</sup> (Longo *Rimondi* Tr. Vol. I 148:3-10.)

proposition that the higher the aspect ratio of a particle, the more likely it is to be asbestiform.<sup>53</sup> And plaintiffs ignore that **83%** of the particles that Drs. Longo and Rigler identify as “asbestos” have an aspect ratio below 20:1.<sup>54</sup> In short, the presence of some long and thin particles does not demonstrate, as plaintiffs must, that Drs. Longo and Rigler reliably analyzed particle morphology using TEM.<sup>55</sup>

For all of these reasons, plaintiffs have failed to show that Drs. Longo and Rigler’s TEM methodology was reliable.

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<sup>53</sup> ISO 22262-1 at 23 (“If any amphibole fibres longer than 5 [micrometers] with aspect ratios in the range of 20:1 or higher are observed, then it can be concluded that amphibole asbestos is *probably* present, *with the degree of certainty increasing with increasing aspect ratio.*”) (emphasis added). ISO 22262-1 also directs the analyst to consider other characteristics in making the ultimate determination. *See id.* at 22-23.

<sup>54</sup> Specifically, only 28 of the 157 particles that Dr. Longo identified had aspect ratios of 20:1 or greater. (*See* 2d Suppl. Longo Rep. at 34-48.)

<sup>55</sup> Plaintiffs argue that “J&J has offered no evidence that the” particles Drs. Longo and Rigler claim to have identified “are likely non-asbestiform” (Pls.’ Opp’n at 64), but it is plaintiffs’ burden to prove the presence of asbestos. And contrary to plaintiffs’ portrayal, defendants’ expert Dr. Mossman did not state that “particles with high-aspect ratios are not cleavage fragments by definition.” (*Id.*) Rather, she testified that cleavage fragments are “rarely” “greater than 5 or 10 microns” with “a narrow diameter.” (Dep. of Brooke T. Mossman, M.S., Ph.D., 51:23-52:4, *Leavitt v. Johnson & Johnson*, No. RG17882401 (Cal. Sup. Ct. Nov.15, 2018) (attached as Ex. 108 to Pls.’ Opp’n).) In other words, while cleavage fragments *tend* to be wider and chunkier than asbestos fibers, that does not mean that every asbestos fiber is longer than every cleavage fragment, or that a long particle cannot be a cleavage fragment.

**B. Plaintiffs Fail To Show That Drs. Longo And Rigler’s SAED Analysis Was Reliable.**

Defendants explained in their opening brief that SAED analysis is an essential step necessary to confirm the mineral type of a particle.<sup>56</sup> To properly analyze a particle under SAED, multiple zone-axis orientation diffraction patterns (images taken at particular angles) are required and analysts must compare their SAED measurements to known data on minerals’ crystal structure. Plaintiffs fail to rebut defendants’ argument that Drs. Longo and Rigler conducted these steps unreliably or failed to conduct them at all.

*First*, Drs. Longo and Rigler rarely used *any* zone-axis diffraction patterns, and when they did, never more than one. As a result, their methodology is not reliable, since the use of multiple zone-axis diffraction patterns is a required element of reliable SAED methodology.<sup>57</sup> In response, plaintiffs first argue half-heartedly that Drs. Longo and Rigler did, in fact, use zone-axis diffraction patterns, and more than one for anthophyllite.<sup>58</sup> But their reports do not disclose this,<sup>59</sup> and Dr. Longo has testified otherwise, stating outright that “[w]e don’t typically take

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<sup>56</sup> (Defs.’ Br. at 50-62.)

<sup>57</sup> (*Id.* at 52-54.)

<sup>58</sup> (Pls.’ Opp’n at 67 (“Drs. Longo and Rigler use one zone axis for tremolite . . . [f]or anthophyllite and anthophyllite solid series solution, MAS and Drs. Longo and Rigler use two zone axes.”).)

<sup>59</sup> (*See* Defs.’ Br. at 54-55.)

zone axis diffraction patterns.”<sup>60</sup> He similarly made clear that for “no particle that [he] designated anthophyllite did [he] take more than one zone axis orientation.”<sup>61</sup> These concessions are dispositive.

In the alternative, plaintiffs argue that multiple zone-axis diffraction patterns are not actually necessary in asbestos detection methodology.<sup>62</sup> But this is wrong as well. Indeed, the very ISO standards Drs. Longo and Rigler purport to rely on require multiple zone-axis patterns. ISO 22262-1 states: “[*O*]*nly* those ED [electron diffraction] patterns obtained when the fibre is oriented with a principal crystallographic axis closely parallel to the incident electron beam direction can be interpreted quantitatively. This type of ED pattern shall be referred to as a zone-axis ED pattern.”<sup>63</sup> It goes on to state that because a single “zone-axis ED pattern obtained by examination of a fibre in a particular orientation can be *insufficiently specific* to permit unequivocal identification of the mineral fibre,” an analyst

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<sup>60</sup> (Dep. of William E. Longo, Ph.D. 102:20-22, *Weirick v. Brenntag N. Am.*, No. BC656425 (Cal. Super. Ct. Apr. 17, 2019) (attached as Ex. E10 to Tersigni Cert.).)

<sup>61</sup> (*Id.* 122:21-25.)

<sup>62</sup> (*See* Pls.’ Opp’n at 69-70 (arguing that defendants’ expert Dr. Dyar only identified the Yamate protocol as requiring multiple zone-axis determinations).)

<sup>63</sup> ISO 22262-1 at 64 (emphasis added); ISO 13794 at 44 (emphasis added) (same). Interpreting the pattern “quantitatively” means interpreting it by measuring the d-spacings and angles. ISO 22262-1 at 64; *see also* ISO 13794 at 6 (“[C]onfirmation of amphibole is only by . . . quantitative zone-axis ED.”).



should “record a *different ED pattern* corresponding to another zone axis.”<sup>64</sup>

Plaintiffs never respond to the fact that Drs. Longo and Rigler’s approach contradicts their own methodology, a quintessential basis for exclusion. *See, e.g., In re Lamar Cty. Order; Amorgianos*, 303 F.3d at 268-69.

Notably, the court in *Hanson* squarely addressed this issue, holding that an expert who claimed to have detected asbestos in talc did not use a reliable methodology because, *inter alia*, he did not use multiple zone-axis diffraction patterns when conducting SAED. *Hanson v. Colgate-Palmolive Co.*, 353 F. Supp. 3d 1273, 1281, 1287 (S.D. Ga. 2018). Plaintiffs ignore the *Hanson* decision, and likewise ignore Dr. Longo’s testimony in which he agreed with it, stating that “[a] minimum of two, maybe three” orientations are needed to “uniquely identify a mineral with SAED.”<sup>65</sup> Although plaintiffs discuss the Yamate Method (which was adopted by the EPA and was at issue in *Hanson*), they ignore that it provides that SAED patterns must be obtained “in near-exact zone axis orientations” and

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<sup>64</sup> ISO 22262-1 at 6 (emphases added); ISO 13794 at 44 (emphases added) (same).

<sup>65</sup> (Longo Dep. 139:9-11.) The *Hanson* decision is particularly on point because, like Drs. Longo and Rigler, the expert there purported to test talc for asbestos but repeatedly deviated from his own methodology, including by not using multiple zone-axis diffraction patterns for SAED and not disclosing data critical to reproducing his results (an issue equally applicable to Drs. Longo and Rigler’s failure to disclose quantitative EDXA data and various internal reference materials). Nevertheless, plaintiffs do not address *Hanson* at all.



that “more than one zone-axis orientation” is required.<sup>66</sup> Although those requirements do not apply to all “Levels” of the Yamate Method,<sup>67</sup> they *do* apply to “Level III,” which is the procedure that is required in “legal case[s],” as Dr. Longo admits.<sup>68</sup> *See also Hanson*, 353 F. Supp. 3d at 1281 (explaining that Level II “is sufficient for regulatory action but not anticipated litigation”).

Finally, plaintiffs argue that Dr. Dyar provides no authority other than the Yamate Method for requiring the use of two zone-axis patterns,<sup>69</sup> but this is wrong. Dr. Dyar identified both the Yamate Method and the ISO protocols discussed above in her report.<sup>70</sup> By contrast, Dr. Longo’s apparent view that following protocol is not necessary “[i]f you do this long enough” is pure *ipse dixit*.<sup>71</sup>

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<sup>66</sup> Yamate et al., *Methodology for the Measurement of Airborne Asbestos by Electron Microscopy* 44 (1984) (“Yamate 1984”) (attached as Ex. A158 to Tersigni Cert.).

<sup>67</sup> (See Pls.’ Opp’n at 69 (generally discussing the different levels).)

<sup>68</sup> (Tr. of Proceedings (“Longo Schmitz Tr.”) 176:11-177:8, *Schmitz v. Johnson & Johnson*, No. RG18923615 (Cal. Super. Ct. Apr. 30, 2019) (attached as Ex. 83 to Pls.’ Opp’n) (admitting that the Yamate Method states that, “if it’s going to be a legal case, . . . *you need to do a couple zone-axis diffraction patterns* to verify”) (emphasis added) (quoted in Pls.’ Opp’n at 69).)

<sup>69</sup> (Pls.’ Opp’n at 69-70.) Because Dr. Dyar disclosed this opinion, it does not matter whether she could “articulate” these sources at her deposition. (*See id.*)

<sup>70</sup> (Dyar Rep. at 29-31 & nn.47, 48, 50.)

<sup>71</sup> (See Pls.’ Opp’n at 68 (alteration in original) (quoting Longo Dep. 183:8-184:2).)

Plaintiffs cite no authority (other than Dr. Longo himself) stating that only one pattern is sufficient or that the pattern can be a non-zone-axis pattern.

*Second*, plaintiffs likewise fail to address the problems with Drs. Longo and Rigler's SAED measurements. For starters, plaintiffs do not refute that there are thousands of minerals that are consistent with Drs. Longo and Rigler's SAED measurements.<sup>72</sup> This is especially problematic because ISO 22262-2 (the protocol Drs. Longo and Rigler purport to follow) states that "demonstration that an ED pattern is consistent with the crystal structure of a particular mineral is not proof of identity, unless the ED pattern has also been shown to be *inconsistent* with the crystal structures of the other possible minerals."<sup>73</sup> Drs. Longo and Rigler have not even attempted to do that, and thus again have "failed to apply [their] own methodology reliably." *Amorgianos*, 303 F.3d at 268-69. Although plaintiffs contend that the consistency with thousands of other minerals is "solely based on the opinions of Dr. Dyar,"<sup>74</sup> it is Dr. Longo's burden to rule out other minerals according to his own methodology. Moreover, Dr. Dyar demonstrated the

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<sup>72</sup> (See Dyar Rep. at 35.)

<sup>73</sup> ISO 22262-1 at 65.

<sup>74</sup> (Pls.' Opp'n at 70.)

consistency with thousands of other minerals by citing standard mineral databases, and her conclusion is unrebutted.<sup>75</sup>

Additionally, plaintiffs do not dispute that there are instances where Drs. Longo and Rigler's measurements also are inconsistent with the tremolite or anthophyllite they purport to identify.<sup>76</sup> Nor do plaintiffs dispute that MAS analysts conducted their analysis only after they had made their judgment calls on what mineral they were seeing.<sup>77</sup> This, too, is a basis to exclude their opinions. *See, e.g., Bracco Diagnostics, Inc. v. Amersham Health, Inc.*, 627 F. Supp. 2d 384, 405, 452 (D.N.J. 2009) (Wolfson, J.) (concluding that expert's post-hoc analysis contravened accepted scientific principles); *Snodgrass v. Ford Motor Co.*, No. 96-1814(JBS), 2002 WL 485688, at \*12 (D.N.J. Mar. 28, 2002) (excluding expert who "determined the conclusion before the hypothesis was put forth").

**Finally**, plaintiffs point to testimony by Dr. Longo stating that "nothing here is done in a vacuum," and that his EDXA analysis confirms his SAED analysis and

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<sup>75</sup> (Dyar Rep. at 35-36 & n.59-61.) Plaintiffs argue that Dr. Dyar did not consider which of the other minerals were likely to be present in the talc mines at issue. (Pls.' Opp'n at 70.) But neither did Drs. Longo and Rigler, and it was **their** burden since they purport to be uniquely identifying anthophyllite and tremolite. Indeed, although Drs. Longo and Rigler purport to have uniquely identified these minerals, they have never indicated that they first narrowed down candidates based on what minerals might be in the mines. (*See* Longo Dep. 65:20-105:17.)

<sup>76</sup> (*See* Defs.' Br. at 59-62.)

<sup>77</sup> (Longo Dep. 182:16-19; Rigler Dep. 117:8-117:12.)

vice versa.<sup>78</sup> But this is nonsensical because, as elaborated in the next section, the non-quantitative EDXA method applied by Drs. Longo and Rigler is incapable of identifying asbestos, making an accurate determination by SAED essential to a reliable asbestos detection methodology. *See Hanson*, 353 F. Supp. 3d at 1280-81 (explaining that asbestos detection analysis for litigation requires both EDXA and SAED).<sup>79</sup> And methodological errors in either of these elements of Drs. Longo and Rigler’s overall methodology suffice to render all of their opinions inadmissible. *See Zoloff*, 858 F.3d at 797 (“*any* step that renders [an expert’s] analysis unreliable under the *Daubert* factors renders the expert’s testimony inadmissible”) (citation omitted).

For all of these reasons, plaintiffs have failed to rebut defendants’ arguments showing that Drs. Longo and Rigler’s SAED analysis was unreliable in numerous respects.

**C. Plaintiffs Fail To Show That Drs. Longo And Rigler’s EDXA Analysis Was Reliable.**

Defendants also explained in their opening brief that reliable analysis of elemental chemistry by EDXA requires quantitative data in order to accurately

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<sup>78</sup> (Pls.’ Opp’n at 68 (quoting Longo Dep. 183:8-184:2); *id.* at 68-69 (citing Longo *Schmitz* Tr. 176:11-177:8).)

<sup>79</sup> Indeed, Dr. Rigler admits that one cannot “identify a particle of asbestos by EDXA alone” because the EDXA result “would be similar to the chemistry of another type of fiber.” (Rigler Dep. 54:3-9.)

determine the ratios of the elements – a step Drs. Longo and Rigler omitted in favor of an unreliable “eyeball” approach that ensures that their conclusions cannot be verified.<sup>80</sup> Plaintiffs deny that Drs. Longo and Rigler’s EDXA determinations were subjective and that the use of quantitative data is required.<sup>81</sup> None of this is correct.

*First*, plaintiffs claim that Drs. Longo and Rigler “don’t make any [EDXA] conclusions by eyeballing it,”<sup>82</sup> but this is merely a game of semantics. Dr. Longo admitted that his analysts were “just visually confirming” the EDXA graph and likely not even “looking at a known reference.”<sup>83</sup> Whatever Dr. Longo wishes to call this methodology, it is subjective and unreliable. *See, e.g., United States v. Schultz*, No. 14-cr-467-3, 2016 WL 7409911, at \*3 (N.D. Ill. Dec. 22, 2016) (excluding handwriting expert who did “little more than subjectively eyeball the various signatures and reach a bottom-line conclusion” and did “not describe any method for comparing handwriting”); *Disabled in Action*, 360 F. Supp. 3d at 244 (excluding expert who eschewed “provid[ing] exact measurements” in favor of an

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<sup>80</sup> (Defs.’ Br. at 62-72.)

<sup>81</sup> (Pls.’ Opp’n at 70-74.)

<sup>82</sup> (*Id.* at 71 (quoting Longo Dep. 92:6-93:25).)

<sup>83</sup> (Longo Dep. 81:10; *id.* 69:2-7.)

informal and unreliable “eye test”).<sup>84</sup> Notably, plaintiffs do not point to any authority or protocol sanctioning the use of subjective visual determinations.

*Second*, plaintiffs’ argument that using quantitative data for EDXA is unnecessary is erroneous. ISO 13794 contains the “[f]ull details relating to identification of asbestos fibres using TEM” under the ISO methodologies<sup>85</sup> and states that “confirmation of amphibole is *only by quantitative EDXA*.”<sup>86</sup> “[Q]uantitative EDXA classification” entails “computer analysis of the net peak areas.”<sup>87</sup> In other words, the raw data calculating the area under the EDXA peaks is required. The Yamate EPA Method also requires that “an image of the spectra is taken *along with a record of the peak heights*.”<sup>88</sup> Newbury and Ritchie requires it as well.<sup>89</sup> And Dr. James Millette – whom Dr. Longo has collaborated with in the

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<sup>84</sup> (See Defs.’ Br. at 69-70 & n.176.)

<sup>85</sup> ISO 22262-1 at 31.

<sup>86</sup> ISO 13794 at 6 (emphasis added)

<sup>87</sup> *Id.* at 46; *see also id.* at 45 (“For quantitative interpretation, the net peak areas, after background subtraction, are obtained for the X-ray peaks originating from the elements in the fibre.”).

<sup>88</sup> Yamate 1984 at 46 (emphasis added).

<sup>89</sup> Newbury & Ritchie, *Performing Elemental Microanalysis with High Accuracy and High Precision by Scanning Electron Microscopy*, 50 J. Mater. Sci 493, 499-500 (2015) (attached as Ex. A171 to Suppl. Tersigni Cert.).

past and has the “highest respect for”<sup>90</sup> – stated that the “raw data sheet . . . should, of course, be reviewed by an experienced analyst before calculations and client reporting.”<sup>91</sup>

For these reasons, plaintiffs are wrong in claiming that “Dr. Dyar cannot even point to a standard that requires a printout of the quantitative data.”<sup>92</sup> Dr. Dyar identified the “Newbury and Ritchie,” “ISO standards” and “EPA requirements” discussed above as support for the need to use quantitative data.<sup>93</sup> And again, it is *plaintiffs’* burden to demonstrate that Drs. Longo and Rigler’s method is reliable, and they cite no scientific authority to support their approach. Instead, they can only point to “the experience and knowledge of MAS and Drs. Longo and Rigler surrounding EDXA identification of asbestos materials.”<sup>94</sup> That is quintessential *ipse dixit*. Moreover, although plaintiffs additionally argue that Dr. Dyar agreed that the raw data are not necessary “if you already know what [the

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<sup>90</sup> (Dep. of William E. Longo, Ph.D. 153:14-15, *Von Salzen v. Am. Int’l Indus. Inc.*, JCCP 4674/No. BC680576 (Cal. Super. Ct. June 27, 2018) (supplemental excerpt attached as Ex. E37 to 2d Suppl. Tersigni Cert.).)

<sup>91</sup> Krewer 1990 at 106.

<sup>92</sup> (Pls.’ Opp’n at 73.)

<sup>93</sup> (Dep. of M. Darby Dyar 125:19-25, 128:16-21, Apr. 2, 2019 (attached as Ex. 91 to Pls.’ Opp’n).)

<sup>94</sup> (Pls.’ Opp’n at 74.)

mineral] is,”<sup>95</sup> that is nonsensical because the whole purpose of Drs. Longo and Rigler’s analysis is to identify what the mineral is in the first place.<sup>96</sup>

In any event, plaintiffs do not refute that Drs. Longo and Rigler’s subjective EDXA determinations cannot be verified without quantitative data. *See, e.g., United States v. Hebshie*, 754 F. Supp. 2d 89, 125 (D. Mass. 2010)

(“Documentation is necessary to test a hypothesis” and “reproducibility is the sine qua non of ‘science.’”); *Zenith Elecs. Corp. v. WH-TV Broad. Corp.*, 395 F.3d 416, 419 (7th Cir. 2005) (“Someone else using the same data and methods must be able to replicate the result.”). Indeed, plaintiffs fail to address testimony by Dr. Longo refusing to say that an experienced third-party EDXA scientist would agree that

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<sup>95</sup> (*Id.* at 73.)

<sup>96</sup> Plaintiffs also fault Dr. Dyar and defendants for not considering Dr. Blount’s 1991 article. (*Id.* at 74.) But that article says nothing about Drs. Longo and Rigler’s methodology since it does not use EDXA at all. *See* Blount, *Amphibole Content of Cosmetic and Pharmaceutical Talcs*, 94 *Env’tl Health Perspectives* 225 (1991) (attached as Ex. 23 to Pls.’ Opp’n). Although plaintiffs have no explanation or citation, they presumably rely on a handwritten notation of unknown origin to argue that “Sample I” in Dr. Blount’s paper is Vermont talc. (Ex. J&J-220, at 9 (attached as Ex. 24 to Pls.’ Opp’n).) Those notations do not even match the article, which says that Dr. Blount tested four foreign talcs, whereas the handwriting only lists three. And Sample I could not be defendants’ talc because Drs. Blount purchased the bottle of defendants’ product she used for testing in 1996, years after the 1991 paper. (Dep. of Alice M. Blount, Ph.D. 47:15-25, *Ingham v. Johnson & Johnson*, No. 1522-CC10417-01 (Mo. Cir. Ct. Apr. 13, 2018) (attached as Ex. E34 to 2d Suppl. Tersigni Cert.).) Finally, it is bizarre that plaintiffs point to Dr. Blount as finding a “consistent” mineral type because Drs. Longo and Rigler found almost entirely anthophyllite and she did not purport to identify *any* anthophyllite.



one of the EDXA graphs he identified as tremolite in fact depicted tremolite.<sup>97</sup> Nor do they address Dr. Rigler's admission that the EDXA graphs could "correspond to a number of other minerals."<sup>98</sup> And they completely ignore the fact that omitting data critical to reproducing an expert's results is "sufficient by itself to exclude" an expert. *Hanson*, 353 F. Supp. 3d at 1285 (excluding expert whose omission of essential data foreclosed the possibility that a "debate could have occurred on a level playing field with all material facts available to everyone as contemplated by *Daubert* and its progeny").<sup>99</sup>

In sum, Drs. Longo and Rigler's EDXA methodology was not reliable and should be excluded, and plaintiffs' arguments to the contrary should be rejected.

**D. Plaintiffs Fail To Show That Drs. Longo And Rigler's PLM Analysis Was Reliable.**

Defendants explained in their opening brief that Drs. Longo and Rigler's PLM analysis was also unreliable for several reasons, including that they used a procedure (ISO 22262-1) that cannot reliably quantify asbestos and that their effort

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<sup>97</sup> (Longo Dep. 122:2-25.)

<sup>98</sup> (Rigler Dep. 66:5-12.)

<sup>99</sup> (*See* Defs.' Br. at 71.) Plaintiffs deny that Drs. Longo and Rigler redacted quantitative EDXA data and attempt to reframe Dr. Longo's "force[d] admission" (which is nevertheless an admission) that he redacted pertinent information from his reports in prior cases. (Pls.' Opp'n at 74-75.) The pattern of behavior and the conspicuous absence of quantitative data in the Longo-Rigler EDXA graphs are evidence that they intentionally avoided reporting these data so as to make their conclusions difficult to disprove. (*See* Defs.' Br. at 66-68, 71.)

to verify their results via a third-party lab (J3 Resources) instead revealed enormous inconsistency.<sup>100</sup> Defendants also noted that Dr. Longo's inexperience with PLM was shown by his inability to tell the difference between an asbestos "bundle" and a cleavage fragment.<sup>101</sup> Plaintiffs' arguments in response are meritless.

As to the procedure, plaintiffs themselves state that "ISO 22262-1 specifically notes '[s]imple analytical procedures such as polarized light microscopy are *not capable of detecting or reliably identifying asbestos* in some types of commercial products.'" <sup>102</sup> They go on to state that "the ISO 22262-2 method is used for the quantitative determination of asbestos," <sup>103</sup> but Drs. Longo and Rigler selected the ISO 22262-1 method, and not -2. They therefore failed to follow the methodology that even plaintiffs acknowledge was required, rendering their approach unreliable and furnishing an independent basis for exclusion of their PLM opinions.

As to inconsistency and reproducibility, plaintiffs do not address any of defendants' cases holding that a lack of reproducibility demonstrates a lack of

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<sup>100</sup> (Defs.' Br. at 75-80.)

<sup>101</sup> (*Id.* at 78-80.)

<sup>102</sup> (Pls.' Opp'n at 59 (alteration in original) (emphasis added) (quoting ISO 22262-1 at vii.).)

<sup>103</sup> (*Id.* (emphasis added).)

reliability. *See, e.g., In re Paoli*, 35 F.3d at 777 (affirming exclusion where a “methodological problem” with the expert’s analysis was that the two tests “produced inconsistent results”); *In re Diet Drugs*, No. MDL 1203, 2001 WL 454586, at \*13 (E.D. Pa. Feb. 1, 2001) (excluding expert who “could not reproduce his own results when . . . using his own method”).<sup>104</sup> Nor do they respond to the fact that Dr. Longo called an image of a known nonasbestiform cleavage fragment an asbestiform “bundle.”<sup>105</sup> Instead, they merely quote **Dr. Longo’s** claims that his inconsistent results are not problematic and that his bundle determinations were based on a reliable methodology. Drs. Longo’s unsupported say-so is plainly insufficient to justify his methodology. *See, e.g., In re TMI Litig.*, 193 F.3d 613, 668, 670, 687 (3d Cir. 1999) (an expert’s opinion is subject to attack when he “relies in part on his own *ipse dixit*, rather than on something more readily verifiable”), *amended in nonmaterial part*, 199 F.3d 158 (3d Cir. 2000).

Plaintiffs also attempt to explain away the fact that J3 Resources failed to detect **any asbestos** in **any sample** via PLM (using the same methodology as Drs. Longo and Rigler), pointing out that the two labs agreed that certain samples did **not** contain asbestos.<sup>106</sup> But this ignores that J3 Resources could not replicate a

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<sup>104</sup> (Defs.’ Br. at 49, 71, 80.)

<sup>105</sup> (*See id.* at 79-80.)

<sup>106</sup> (Pls.’ Opp’n at 78.)

single positive PLM result from MAS, which is the key issue given that plaintiffs and Drs. Longo and Rigler are seeking to prove the presence, not absence, of asbestos. Plaintiffs offer several speculative excuses for this lack of reproducibility, guessing that it might relate to “the time [spent analyzing], high resolution, aberration-corrected lenses, [and] [real-time view] digital cameras”<sup>107</sup> that were “employed exclusively by MAS.”<sup>108</sup> To the extent plaintiffs are implying that J3 conducted a poor analysis, this self-serving suggestion contradicts Dr. Longo’s view that J3 is “a good lab”<sup>109</sup> and that he would “expect an analyst in [his] lab and an analyst in [J3] to get the same results for a particular bottle.”<sup>110</sup> In any event, the notion that the labs generated inconsistent results because one of them did not spend sufficient time or resources is pure speculation.<sup>111</sup>

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<sup>107</sup> (*Id.* at 79 (alterations in original) (quoting Trial Tr. 189:22-190:12, *Leavitt v. Johnson & Johnson*, No. RG17882401 (Cal. Super. Ct. Feb. 7, 2019)).)

<sup>108</sup> (*Id.*)

<sup>109</sup> (Longo *Anderson* Dep. 67:13-14.)

<sup>110</sup> (Longo Dep. 57:22-58:8.)

<sup>111</sup> Contrary to plaintiffs’ claims (Pls.’ Opp’n at 80), it is accurate that there were as many instances where Drs. Longo and Rigler reported detects by ISO PLM where they did not by Blount PLM as there were instances where they reported detects by Blount PLM but not ISO PLM. For sample numbers M68503-004, M69042-009 and M68503-057, they reported detects by ISO PLM but not Blount PLM. (2d Suppl. Longo Rep. at 33, 36.) And for sample numbers M68503-010, M68503-009 and M68503-28, they reported detects by Blount PLM but not ISO PLM. (*Id.*)

Finally, plaintiffs do not dispute that the MAS analysts reached their conclusions regarding the concentrations of asbestos they purported to find through internal standards that were neither disclosed nor produced.<sup>112</sup> This, too, requires their exclusion. *See Bracco*, 627 F. Supp. 2d at 446 (striking portion of expert’s survey based on web-page recreations that “were never produced” but were “critical to obtaining accurate and reliable survey results”); *Hanson*, 353 F. Supp. 3d at 1285 (excluding expert who failed to produce data needed for verification).

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In sum, Drs. Longo and Rigler’s microscopy methodologies are fundamentally unscientific and unreliable, and plaintiffs’ arguments to the contrary, most of which are supported only by Dr. Longo’s *ipse dixit*, should be rejected.

### **III. PLAINTIFFS HAVE NO SUPPORT FOR THE THEORY THAT THE LEVELS AND TYPES OF ASBESTOS ALLEGED TO BE PRESENT IN THE PRODUCTS CAUSE OVARIAN CANCER.**

Even if the Court ignored the many serious flaws in Longo and Rigler’s opinions, plaintiffs’ asbestos theories would remain inadmissible and irrelevant because they have no reliable evidence that the amount and type of asbestos alleged to be present in the Products could ever cause ovarian cancer. Indeed, as defendants explained in their opening brief, the contention that *any* amount of *any*

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<sup>112</sup> (Defs.’ Br. at 75 & n.191.)

type of asbestos can cause ovarian cancer is still an open question in the scientific community.<sup>113</sup>

Plaintiffs resist this conclusion, largely by recounting the findings of IARC and one meta-analysis that “supported the conclusion by IARC.”<sup>114</sup> But, as defendants explained in their opening brief, those studies have significant limitations, especially because of the likelihood of misdiagnosis, leading scientists to conclude that IARC’s classification of asbestos as an ovarian carcinogen was “premature” and that further research is needed in this area.<sup>115</sup>

In any event, defendants explained in their opening brief that even assuming there is a causal relationship between asbestos and ovarian cancer, plaintiffs’ causal theories would still be unreliable and unsupported because: (1) the levels of asbestos that Longo and Rigler claim to have found in the Products come nowhere

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<sup>113</sup> (Defs.’ Br. at 20-23, 81-83.)

<sup>114</sup> (See Pls.’ Opp’n at 88-89.) Plaintiffs also rely on one study – Heller 1996 – that found significant asbestos fiber burdens in nine of 13 women with only household asbestos exposure. (*Id.* at 88 (citing Heller et al., *Asbestos Exposure and Ovarian Fiber Burden*, 29(5) Am. J. of Industrial Med. 435 (1996) (attached as Ex. A59 to Tersigni Cert.)).) But plaintiffs gloss over the fact that the study on which they rely also found significant fiber burdens in six of 17 women who had no known exposure to asbestos. If anything, the Heller study provides support for **defendants’** position because it establishes that women with no known exposure to asbestos can have fiber burdens in their ovarian tissue.

<sup>115</sup> (See Defs.’ Br. at 81-83.) See also, e.g., Reid et al., *Does Exposure to Asbestos Cause Ovarian Cancer? A Systematic Literature Review and Meta-Analysis*, 20(7) Cancer Epidemiol. Biomarkers & Prev. 1287, 1287, 1294 (2011) (“Reid 2011”) (attached as Ex. A118 to Tersigni Cert.).

close to the occupational exposure levels at which IARC concluded that exposure can cause cancer; (2) the Products allegedly contain different types of asbestos from those at issue in the studies cited in support of a causal relationship; and (3) plaintiffs are essentially advancing an unreliable any-exposure theory of causation.<sup>116</sup> Plaintiffs barely respond to these arguments, but to the extent they do, their responses lack merit.

**A. Plaintiffs Have Offered No Evidence That The Levels Of Asbestos Alleged By Drs. Longo And Rigler Could Possibly Cause Ovarian Cancer.**

As set forth in defendants' opening brief, plaintiffs have no evidence that the amount of asbestos Longo and Rigler claim to have found in the Products could ever cause ovarian cancer; indeed, even using the highest concentrations they claim to have found, 50-year exposure levels would be *thousands of times lower* than exposure levels considered safe by OSHA and the literature.<sup>117</sup> Plaintiffs barely respond to this contention, arguing only that IARC did not limit its findings to occupational exposures and that *defendants* have not proffered any evidence showing that exposure to asbestos in the Products would be lower than

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<sup>116</sup> (Defs.' Br. at 83-93.)

<sup>117</sup> (*Id.* at 83-87.)

occupational exposure levels.<sup>118</sup> These arguments badly misperceive the burden of proof – which rests with plaintiffs, not defendants – and in any event lack merit.

*First*, plaintiffs’ focus on whether IARC purported to limit its finding to occupational exposures<sup>119</sup> is misplaced. What matters is what the underlying *studies* addressed, and it is undisputed that while occupational studies have found statistically significant associations between asbestos exposure and ovarian cancer, no non-occupational study has done so.<sup>120</sup> Indeed, IARC itself described the studies driving its conclusion as those involving “heavy occupational exposure”;<sup>121</sup> plaintiffs’ preferred meta-analysis by Camargo and others in 2011 was expressly limited to occupational exposures and itself characterized IARC’s finding as one relating to “occupational exposure to asbestos”;<sup>122</sup> and the other 2011 meta-analysis of this issue noted that while “many women in epidemiologic studies have

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<sup>118</sup> (Pls.’ Opp’n at 85-86.)

<sup>119</sup> (*Id.*)

<sup>120</sup> (*See* Defs.’ Br. at 83-87 & n.215.)

<sup>121</sup> Int’l Agency for Research on Cancer, World Health Org., 100 *Monographs on the Evaluation of Carcinogenic Risks to Humans: Arsenic, Metals, Fibres, and Dusts* 220, 256 (2012) (“IARC 2012 Monograph”) (attached as Ex. A70 to Tersigni Cert.).

<sup>122</sup> Camargo et al., *Occupational Exposure to Asbestos and Ovarian Cancer: A Meta-Analysis*, 119 *Envtl. Health Perspectives* 1211 (2011) (“Camargo 2011”) (attached as Ex. A59 to Tersigni Cert.). (*See* Pls.’ Opp’n at 88-89 & n.312 (citing Camargo 2011 as support).) Plaintiffs erroneously assert that the Camargo analysis “evaluate[d] this association in occupational and non-occupational settings” (*id.* at 89), but it was in fact limited to occupational exposures.



had domestic or general environmental exposure, levels have been relatively low so that risks and hence numbers of cases have also been few.”<sup>123</sup> In short, there is ***no scientific evidence*** that asbestos exposures at levels below heavy occupational exposure can cause ovarian cancer – and plaintiffs do not cite a single study or analysis suggesting otherwise anywhere in their 107-page brief.

***Second***, plaintiffs’ argument that “J&J cites no support for its assertion that occupational exposure would be greater than the exposure of a women [sic] who applies talcum powder to her genital area regularly”<sup>124</sup> is wrong at multiple levels. As already noted, this argument misrepresents the burden of proof on causation, which is exclusively plaintiffs’. *See Holbrook v. Lykes Bros. S.S. Co.*, 80 F.3d 777, 786 (3d Cir. 1996) (defendants did not bear the burden of proving the cause of plaintiff’s cancer); *see also Aycock v. R.J. Reynolds Tobacco Co.*, 769 F.3d 1063, 1069-70 (11th Cir. 2014) (district court improperly shifted the burden of proof by requiring defendants to provide alternative theory of causation; the district court “placed the burden of proof as to causation on the wrong party”); *Childress v. Johnson & Johnson*, No. 2:12-cv-01564, 2017 WL 6348621, at \*2 (S.D. W. Va. Dec. 12, 2017) (defendants “do not bear the burden of proving causation”).

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<sup>123</sup> Reid 2011 at 1287.

<sup>124</sup> (Pls.’ Opp’n at 86.)

Regardless of the burden of proof, plaintiffs’ argument that “heavy occupational” exposure could equate to asbestos exposure through cosmetic talcum powder use defies common sense. The occupational asbestos studies describe extreme exposure scenarios – in one instance, for example, women who worked “by hand” with raw crocidolite, which was used in gas masks made for World War II.<sup>125</sup> It defies credulity to suggest that momentary daily exposures to talcum powder – some tiny fraction of which is alleged to consist of asbestos – could possibly compare to exposures involved in handling raw asbestos as a full-time job.

Moreover, plaintiffs ignore that defendants *did* supply evidence that quantifies the vast chasm between the alleged degree of exposure implicated by Longo and Rigler’s findings and other significant exposure metrics. As explained in defendants’ opening brief, even the highest amounts of asbestos that Longo and Rigler claim to have found in the Products would result in cumulative lifetime exposures that are *three times less* than those associated with ambient, background exposure, at least *4,000 times below* the lifetime asbestos concentration associated with the OSHA permissible exposure limit; and at least *29,000 times below* the

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<sup>125</sup> See Acheson et al., *Mortality of Two Groups of Women Who Manufactured Gas Masks from Chrysotile and Crocidolite Asbestos: A 40-Year Follow-Up*, 39 Br J Ind Med 344, 347 (1982) (attached as Ex. A2 to Tersigni Cert.) (citation omitted).

level of tremolite asbestos considered protective of mesothelioma.<sup>126</sup> Plaintiffs offer nothing in response.<sup>127</sup>

In short, plaintiffs have not presented any reliable evidence that the concentrations of asbestos Longo and Rigler claim to have found in the Products could ever cause ovarian cancer.

**B. Plaintiffs’ Experts’ Opinions Regarding Asbestos Are Unreliable Because They Are Based On Studies Regarding Types Of Asbestos That Plaintiffs’ Experts Did Not Claim To Identify In The Products.**

As explained in defendants’ opening brief, the studies finding an association between asbestos and ovarian cancer – on which plaintiffs’ experts rely – “generally involve exposure to crocidolite asbestos,” a type of asbestos that Drs. Longo and Rigler do not purport to have found in the Products.<sup>128</sup> Plaintiffs respond that their experts relied on IARC’s review of the relevant literature, and that the IARC Working Group “evaluated and relied on studies that included chrysotile and amosite asbestos, not just crocidolite asbestos.”<sup>129</sup> Plaintiffs’

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<sup>126</sup> (See Defs.’ Br. at 85 (citing Expert Report of H. Nadia Moore, Ph.D., D.A.B.T., E.R.T. at 52-56, Feb. 25, 2019).)

<sup>127</sup> Nor do plaintiffs’ motions to exclude defendants’ experts’ opinions in any way address this exposure quantification, which is offered by Dr. Nadia Moore. While plaintiffs have moved to exclude other portions of Dr. Moore’s opinions, their motion does not address this opinion.

<sup>128</sup> (Defs.’ Br. at 23.)

<sup>129</sup> (Pls.’ Opp’n at 87.)

argument should be rejected. Although certain studies involved exposure to chrysotile and amosite asbestos (as defendants acknowledged in their opening brief),<sup>130</sup> IARC and subsequent studies analyzing the science have made clear that crocidolite was the “predominant[ ]” form of asbestos at issue in the studies that found a positive association between asbestos and ovarian cancer.<sup>131</sup> And in any event, it is irrelevant whether IARC or any study found a connection between exposure to chrysotile, crocidolite, or amosite asbestos and ovarian cancer because *none of plaintiffs’ experts has identified these types of asbestos in the Products.*<sup>132</sup> In short, plaintiffs’ experts’ failure to base their analyses on studies

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<sup>130</sup> (Defs.’ Br. at 23-24 & n.72.)

<sup>131</sup> See Camargo 2011 at 1215 (noting that “[c]ohorts predominately exposed to crocidolite or mixed [i.e., crocidolite and chrysotile] asbestos showed larger SMRs than did those exposed only to chrysotile asbestos”); IARC 2012 Monograph at 242 (discussing studies finding no excess mortality for cancer of the pharynx in amosite asbestos miners but an excess mortality rate for crocidolite miners and a higher risk rate for factory workers exposed to crocidolite than workers exposed to chrysotile); IARC 2012 Monograph at 254-55 (relying on studies that involved crocidolite and, in some cases, also chrysotile).

<sup>132</sup> Although Cook and Krekeler claim that there was chrysotile asbestos in defendants’ Vermont and Chinese talc mines, those opinions are not reliable for the reasons explained in defendants’ opening brief and *infra*. Moreover, neither Cook nor Krekeler (nor any other expert) has connected chrysotile asbestos to the Products. (See generally Am. Expert Report of Robert B. Cook, Ph.D. (“Am. Cook Rep.”), Jan 22, 2019 (attached as Ex. C2 to Tersigni Cert.); Expert Report of Mark Krekeler, Ph.D. (“Krekeler Rep.”), Nov. 16, 2018 (attached as Ex. C31 to Tersigni Cert.))

involving the same type of asbestos that plaintiffs were allegedly exposed to is yet another methodological flaw that warrants exclusion of their experts' testimony.<sup>133</sup>

**C. Plaintiffs' "Any Exposure" Theory Of Causation Is Unscientific And Unreliable.**

For the reasons discussed above, and explained in defendants' opening brief, plaintiffs' experts' opinions boil down to the sort of "[a]ny [e]xposure" theories that have been widely rejected by courts.<sup>134</sup> In response, plaintiffs assert that they need not address this issue because the alleged presence of asbestos in any amount "provides a credible biologic explanation for the association between talcum powder use and ovarian cancer."<sup>135</sup>

This argument should be rejected as frivolous and disingenuous. If plaintiffs seek to argue that talc contains sufficient asbestos to cause cancer, then they need to show how much asbestos it contains, identify studies finding an association between that level of asbestos and ovarian cancer and conduct a complete Bradford Hill analysis. They have not done so. Even accepting all of Longo and Rigler's unreliable testing, they cannot show any association (let alone a clear-cut association) between the levels of asbestos they report and ovarian cancer. Nor

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<sup>133</sup> (See Defs.' Br. at 87-89 (citing cases holding that an expert's opinion is unreliable if it relies on evidence regarding types of asbestos fibers that are not alleged to be present in the defendant's products).)

<sup>134</sup> (See Defs.' Br. at 89-90 (emphasis omitted) (citing cases).)

<sup>135</sup> (*Id.* at 92-93.)

can plaintiffs use asbestos to patch up the gaping biological plausibility hole in their talc theory.<sup>136</sup> As defendants have repeatedly explained, if plaintiffs are right that talc contains asbestos, then all the relevant studies involved talc contaminated with asbestos, and not one supports plaintiffs' biological plausibility theories.

For all of these reasons, and the reasons explained in defendants' opening brief, plaintiffs' experts' asbestos opinions should all be excluded under *Daubert*.

#### **IV. PLAINTIFFS LACK RELIABLE SCIENTIFIC EVIDENCE THAT ASBESTOS WAS PRESENT IN THE TALC ORE USED TO SOURCE THE PRODUCTS.**

Plaintiffs also fail to resuscitate the opinions of Drs. Cook and Krekeler – two geologists who seek to bolster Drs. Longo and Rigler's conclusions by

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<sup>136</sup> Plaintiffs are incorrect in implying that Michael Huncharek, M.D. and Joshua Muscat, Ph.D., admitted that the presence of asbestos in the Products would present a biologically plausible mechanism for the Products to cause ovarian cancer. (See Pls.' Opp'n at 91-93.) While Drs. Huncharek and Muscat recognized that the presence of asbestos in the Products "could possibly represent a carcinogenic risk" in general, they did not in any way conclude that there is a connection between asbestos exposure at the levels alleged by plaintiffs here and ovarian cancer. Huncharek & Muscat, *Perineal Talc Use and Ovarian Cancer Risk: A Case Study of Scientific Standards in Environmental Epidemiology*, 20 Eur. J. Cancer Prev. 501, 505 (2011) ("Huncharek 2011") (attached as Ex. 118 to Pls.' Opp'n.). Moreover, in both of the articles plaintiffs cite, Drs. Huncharek and Muscat ultimately concluded that the epidemiological evidence did not support a causal relationship between the use of talc and ovarian cancer. Huncharek et al., *Use of Cosmetic Talc on Contraceptive Diaphragms and Risk of Ovarian Cancer: A Meta-Analysis of Nine Observational Studies*, 16 Eur. J. Cancer Prev. 422 (2007) (attached as Ex. A68 to Tersigni Cert.) (finding no association between talc-dusted diaphragms and ovarian cancer development); Huncharek 2011 at 501 (abstract) (concluding "that the weak statistical associations observed in a number of epidemiological studies do not support a causal association").

testifying that asbestos was present in the raw talc ore used to source the Products. These experts' opinions are not supported by the materials they cite, and Dr. Krekeler, who is not a medical professional, has no business opining that cleavage fragments pose health risks to humans.

**A. Plaintiffs' Experts' Opinions Regarding The Alleged Presence Of Asbestos In Talc Ore Are Not Supported By The Data On Which They Rely.**

As explained in defendants' opening brief, Drs. Cook and Krekeler's opinions that the talc ore used to source the Products contained asbestos are inherently unreliable for several reasons. First, both experts premise their opinions in large part on an identical chart summarizing talc testing results that they admit was compiled by plaintiffs' attorneys, which is not a reliable methodology.<sup>137</sup> Second, even putting aside counsel's involvement, the experts have admitted that many of the materials and testing results on which they rely do not relate to the talc ore used in the Products and/or do not actually indicate that asbestos was identified. As set forth below, plaintiffs' responses lack merit.

**1. Drs. Cook And Krekeler Unreliably Base Their Opinions On Counsel-Generated Collections And Summaries Of Documents.**

Both Drs. Cook and Krekeler include in their reports, and base their opinions on, multi-page charts compiling and summarizing a subset of talc-testing

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<sup>137</sup> (See Defs.' Br. at 94-96.)

documents that the experts assert indicate the presence of asbestos in the talc ore used to source the Products.<sup>138</sup> Plaintiffs do not dispute that these charts were created by counsel; nor could they, since both experts testified to that fact at their depositions.<sup>139</sup> Instead, plaintiffs insist that Drs. Cook and Krekeler “contributed” to the charts by “request[ing]” their creation and “review[ing] the underlying documents” and final product.<sup>140</sup> But the experts’ testimony makes clear that the charts are *not* the experts’ work. Indeed, when asked about the chart at his deposition, Dr. Cook could not say with certainty that he had reviewed all of the documents that were included on it, noting only that he “[thought]” he did.<sup>141</sup> And Dr. Krekeler was unwilling to say that he had any role in drafting or editing the chart.<sup>142</sup> This is highly concerning given that the chart goes beyond merely organizing documents, but also includes interpretations of “[w]hat tests revealed,” which are nearly identical in both reports and were therefore presumably drafted by plaintiffs’ counsel.<sup>143</sup> Moreover, questioning of both Dr. Cook and Dr.

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<sup>138</sup> (See Am. Cook Rep. at 13-21; Krekeler Rep. at 14-23.)

<sup>139</sup> (See Defs.’ Br. at 95-96.)

<sup>140</sup> (Pls.’ Opp’n at 95-97.)

<sup>141</sup> (Dep. of Robert Cook, Ph.D. (“Cook Dep.”) 60:6-8, Jan. 30, 2019 (attached as Ex. B43 to Tersigni Cert.).)

<sup>142</sup> (Dep. of Mark Krekeler, Ph.D. (“Krekeler Dep.”) 40:6-15, Jan. 25, 2019 (attached as Ex. B34 to Tersigni Cert.).)

<sup>143</sup> (See Am. Cook Rep. at 13-21; Krekeler Rep. at 14-23.)



Krekeler revealed that neither had a strong grasp of the information included in the charts. Specifically, Dr. Cook testified that he could not say with confidence whether every testing document listed related to testing of talc ore actually used in the Products.<sup>144</sup> And Dr. Krekeler admitted that there was information in the chart that was not accurate and “that [he] was unaware of” the inaccuracies.<sup>145</sup> In other words, the experts’ own testimony indicates that they had minimal involvement in the creation of the chart, which forms a significant basis for their opinions.

Plaintiffs’ argument that the documents Drs. Cook and Krekeler reviewed necessarily had to have been selected by plaintiffs’ counsel because the J&J defendants did not produce materials directly to the experts<sup>146</sup> is a red herring and should be rejected. In any litigation, documents are provided to experts by the parties. But here, plaintiffs’ counsel went far beyond that and provided Drs. Cook and Krekeler with an *analysis* of a select collection of documents – i.e., conclusions regarding “[w]hat tests revealed” – that was directly inserted into the experts’ reports as if they had prepared it. As explained in the J&J defendants’ opening brief, this is a major flaw in the methodologies Drs. Cook and Krekeler used to reach their opinions.

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<sup>144</sup> (See Cook Dep. 368:22-369:3.)

<sup>145</sup> (See Krekeler Dep. 262:11-23.)

<sup>146</sup> (Pls.’ Opp’n at 97-98.)

Plaintiffs' efforts to distinguish the case law cited in the J&J defendants' briefing are also unavailing. For example, plaintiffs argue that defendants' reliance on *State Farm Fire & Casualty Co v. Electrolux Home Products, Inc.*, 980 F. Supp. 2d 1031 (N.D. Ind. 2013), is misplaced because the experts' opinions in that case were not specifically excluded on the basis that the experts relied on materials compiled by counsel.<sup>147</sup> But *State Farm* stands for the general proposition that expert testimony that "merely parrots information provided to [the expert] by a party is generally excluded." 980 F. Supp. 2d at 1048. As the court explained there, "when an expert relies upon information given to him by a party or counsel, [she] must independently verify that information before utilizing it in [her] calculations." *Id.* (citation omitted). The evidence in the record demonstrates that Drs. Cook and Krekeler failed to do that here.<sup>148</sup>

In short, Drs. Cook and Krekeler's wholesale adoption of plaintiffs' counsel's analysis of the evidence does not constitute a reliable scientific method, and as such, their opinions should be excluded.

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<sup>147</sup> (Pls.' Opp'n at 96 (addressing *State Farm*, 980 F. Supp. 2d 1031).)

<sup>148</sup> Plaintiffs also attempt to distinguish *Crowley v. Chait*, 322 F. Supp. 2d 530 (D.N.J. 2004), arguing that the expert there did "little independent research," while Cook and Krekeler both conducted their own review of the materials included on the counsel-created chart. (Pls.' Opp'n at 96-97.) But Drs. Cook and Krekeler's admitted lack of familiarity with those materials indicates that is not the case.

2. The Counsel-Selected Documents On Which Drs. Cook And Krekeler Rely Do Not Provide A Reliable Basis For Their Conclusions.

Even putting aside Drs. Cook and Krekeler's adoption of, and reliance on, the analysis of counsel, the opinions offered Drs. Cook and Krekeler are still unreliable because: (1) a number of the testing documents on which they base their conclusions have nothing to do with the talc used to source the Products; and (2) Drs. Cook and Krekeler have no basis to conclude that asbestiform – as opposed to nonabestiform – minerals were identified in the vast majority of the samples tested.<sup>149</sup> None of plaintiffs' arguments in response has merit.

*First*, plaintiffs generally concede that a number of the testing documents on which Drs. Cook and Krekeler base their opinions do not relate to talc ore that would have been included in the Products, but urge the Court to ignore these “mistakes” because such testing results were “inadvertently included” in the experts' reports.<sup>150</sup> This argument should be rejected because the admitted errors are pervasive in the reports and invalidate the experts' entire methodology by showing that they made no effort to rigorously analyze which testing reports were relevant and which were not. *See, e.g., E.E.O.C. v. Freeman*, 778 F.3d 463, 466 (4th Cir. 2015) (affirming district court's exclusion of expert testimony where

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<sup>149</sup> (See Defs.' Br. at 96-103.)

<sup>150</sup> (Pls.' Opp'n at 93, 99.)

“[t]he district court identified an alarming number of errors and analytical fallacies in Murphy’s reports, making it impossible to rely on any of his conclusions”).

**Second**, plaintiffs argue that it was appropriate for Drs. Cook and Krekeler to consider test results and other materials unrelated to the mines used to source the Products because they pertained to talc from the same general regions as those mines.<sup>151</sup> But, as noted in the J&J defendants’ opening brief, even plaintiffs’ own experts have agreed that each talc deposit is unique and must be evaluated individually to determine which minerals are present.<sup>152</sup> Thus, data relating to talc taken from mines that were not used to source the Products cannot support Drs. Cook and Krekeler’s conclusions that the talc ore used in the Products contained asbestos. Moreover, some of the materials Cook and Krekeler rely on relate to the geography of (and samples taken from) ore that is *thousands of miles away* from the Vermont, Italian and Chinese talc mines used to source the Products at issue.<sup>153</sup> These materials have zero bearing on the issues in this litigation.

**Third**, plaintiffs are incorrect that there is a question of fact as to whether Drs. Cook and Krekeler relied on testing results of *non-ore* specimens that never

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<sup>151</sup> (Pls.’ Opp’n at 99-101.)

<sup>152</sup> (See Cook Dep. 166:8-23 (agreeing that one would need to “look at the individual deposit” to determine its composition); see also Expert Report of Ann G. Wylie, Ph.D. at 18-19, Feb. 25, 2019 (attached as Ex. C6 to Tersigni Cert.) (explaining that “every deposit is unique in some way(s)”).)

<sup>153</sup> (Defs.’ Br. at 98-100.)

would have made it into the Products.<sup>154</sup> Plaintiffs themselves concede that – as noted in the J&J defendants’ opening brief – the “Pooley Report,” upon which Drs. Cook and Krekeler heavily rely, involved testing of Italian talc “samples that were not talc ore.”<sup>155</sup> Nevertheless, they argue that a single sample addressed in the report was referred to as a “specimen of talc ore,” rendering it relevant.<sup>156</sup> But plaintiffs fail to mention that the report goes on to state that the tremolite identified in this sample – which was *not identified as being asbestiform* – was from an “inclusion in a garnet mineral grain,” which would not have been included in talc used to source the Products.<sup>157</sup> Indeed, the report specifically notes that any “tremolite [identified in the report] was associated with carbonate minerals, namely magnesite and calcite[;] *no tremolite was detected in the talc-type specimens.*”<sup>158</sup> Thus, the “Pooley Report” cannot reliably support Drs. Cook and Krekeler’s opinions that there was asbestos in the talc ore used to source the Products.

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<sup>154</sup> (Pls.’ Opp’n at 103 (citation omitted).)

<sup>155</sup> (*Id.*)

<sup>156</sup> (*Id.* (quoting JNJ 000322351-475 at JNJ 000322385 (attached as Ex. D2 to Tersigni Cert.)))

<sup>157</sup> (JNJ 000322351-475 at JNJ 000322396; Expert Report of Mary Poulton, Ph.D. at 6, Feb. 25, 2019 (attached as Ex. C32 to Tersigni Cert.) (explaining that the tremolite identified in Sample I.41 only contained tremolite as an inclusion in a garnet mineral grain).)

<sup>158</sup> (JNJ 000322351-475 at JNJ 000322474.)

*Third*, plaintiffs admit that Drs. Cook and Krekeler rely on test results that generically identify amphiboles, such as tremolite, in talc samples, but ***do not state that the asbestiform varieties of these minerals were found.***<sup>159</sup> Plaintiffs contend, however, that their experts properly relied on these tests as evidence that there is asbestos in the Products because any ambiguity as to whether a mineral is asbestiform “is something for the jury to consider.”<sup>160</sup> Once again, this would turn *Daubert* on its head. As explained in the J&J defendants’ opening brief, the law is clear that expert opinions are not reliable – and are therefore inadmissible – where, as here, they are not supported by the evidence relied upon by the expert.<sup>161</sup> Further, expert testimony is inadmissible when there is too great an analytical gap between the expert’s opinion and the data on which the expert relies. *See Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997); *Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 159 (3d Cir. 1999) (expert’s testimony was properly excluded because it “did not reliably flow from th[e] data and methodology”). That is precisely the case here. As set forth in the J&J defendants’ opening brief, Drs. Cook and Krekeler

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<sup>159</sup> (See Pls.’ Opp’n at 104.)

<sup>160</sup> (*Id.*)

<sup>161</sup> (See Defs.’ Br. at 97 (citing *Bowers v. Nat’l Collegiate Athletic Ass’n*, 564 F. Supp. 2d 322, 353-54 (D.N.J. 2008); *In re Baycol Prods. Litig.*, 532 F. Supp. 2d 1029, 1042 (D. Minn. 2007); *Finestone v. Fla. Power & Light Co.*, No. 03-14040-CIV, 2006 WL 267330, at \*12 (S.D. Fla. Jan. 6, 2006); and *Anderson v. Bristol Myers Squibb Co.*, No. Civ.A. H-95-0003, 1998 WL 35178199, at \*11 (S.D. Tex. Apr. 20, 1998)).)

have conceded that not all tremolite (or other amphiboles) are asbestos; asbestos only occurs when these minerals form in the rare asbestiform habit.<sup>162</sup> As a result, testing results that merely reference tremolite or other amphiboles, with no indication that they are asbestiform, cannot reliably support an opinion that the samples tested contain asbestos. To the contrary, this is rank speculation.

For all of these reasons, plaintiffs' attempts to defend Drs. Cook and Krekeler's unreliable and unsupported opinions that the talc ore used in the Products contains asbestos fail.

**B. Dr. Krekeler Lacks A Reliable Basis For His Opinions That Cleavage Fragments Are "Asbestiform Particles" That Carry Health Risks For Humans.**

As explained in defendants' opening brief, Dr. Krekeler's opinions that cleavage fragments are asbestos and carry the same health effects as asbestos are unscientific and unreliable.<sup>163</sup> Plaintiffs' responses are entirely meritless and unpersuasive.

*First*, plaintiffs contend that Dr. Krekeler's unsupported assertion that a non-asbestiform mineral can be "chang[ed]" into asbestos is an area of "disagreement" among experts and therefore should be "presented to a jury."<sup>164</sup> Again, this

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<sup>162</sup> (Defs.' Br. at 102.)

<sup>163</sup> (See Defs.' Br. at 104-09.)

<sup>164</sup> (See Pls.' Opp'n at 105.)

argument essentially asks the Court to abrogate *Daubert*. As explained in detail in the J&J defendants’ opening brief, an expert opinion is only valid if it is based on reliable science; an expert’s *ipse dixit* is not admissible.<sup>165</sup> Here, the only support plaintiffs can identify for the novel proposition that a nonasbestiform mineral becomes asbestos if it breaks into cleavage fragments is Dr. Krekeler’s own say-so. Notably, plaintiffs (like Dr. Krekeler himself) are unable to point to a single article, report or other published authority that supports this position. Nor do they dispute that even Dr. Longo disagrees with Dr. Krekeler on this point.<sup>166</sup> Plaintiffs also fail to address the copious scientific authorities cited in the J&J defendants’ opening brief, which make clear that minerals that do not grow in the asbestiform habitat cannot become asbestiform due to external manipulation.<sup>167</sup>

***Second***, plaintiffs insist that Dr. Krekeler is qualified to offer an opinion that cleavage fragments pose the same health risks as asbestos – despite his lack of any medical background – because he generally teaches students about the “benefits and risks” of minerals in his work as a geology professor.<sup>168</sup> This argument should be rejected for all of the reasons explained in defendants’ briefing in support of

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<sup>165</sup> (See, e.g., Defs.’ Br. at 106.)

<sup>166</sup> (*Id.* at 105; Longo *Rimondi* Tr. Vol. I 142:13 (Dr. Longo testifying that “[i]f it’s a cleavage fragment it is not asbestos”).)

<sup>167</sup> (See Defs.’ Br. at 105-06.)

<sup>168</sup> (Pls.’ Opp’n at 106.)



their Motion to Exclude Certain Plaintiffs’ Experts’ Opinions for Lack of Qualifications. Plaintiffs also offer the entirely illogical argument that Dr. Krekeler’s opinions regarding the purported health risks of cleavage fragments should be permitted despite his lack of qualifications because they “were not intended as health-related opinions” and instead are simply “statements of fact learned throughout his education and training.”<sup>169</sup> But plaintiffs are, unsurprisingly, unable to explain how an opinion that a substance has “dangerous health effects” akin to those posed by asbestos is not a health-related opinion.<sup>170</sup> Further, it is simply untrue that Dr. Krekeler is merely repeating “facts.” As the J&J defendants explained in detail in their opening brief, neither of the scientific sources Dr. Krekeler cites as support for his opinion that cleavage fragments pose health risks stands for that proposition.<sup>171</sup> Notably, plaintiffs offer no response to this in their opposition.

For all of these reasons, and those set forth in the J&J defendants’ opening brief, the opinions of Drs. Cook and Krekeler are methodologically unreliable and unsupported by science and should therefore be excluded under *Daubert*.

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<sup>169</sup> (*Id.*)

<sup>170</sup> (*See* Krekeler Dep. 114:4-20 (quoting Krekeler Rep. at 4).)

<sup>171</sup> (*See* Defs.’ Br. at 107-08.)

## **CONCLUSION**

For the foregoing reasons, defendants respectfully request that the Court exclude plaintiffs' experts' opinions regarding the alleged presence of asbestos in the Products.

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s/Susan M. Sharko  
Susan M. Sharko  
DRINKER BIDDLE & REATH LLP  
600 Campus Drive  
Florham Park, New Jersey 07932  
Telephone: 973-549-7000  
Facsimile: 973-360-9831  
E-mail: susan.sharko@dbr.com

John H. Beisner  
Jessica D. Miller  
SKADDEN, ARPS, SLATE,  
MEAGHER & FLOM LLP  
1440 New York Avenue, N.W.  
Washington, D.C. 20005  
202-371-7000

*Attorneys for Defendants Johnson &  
Johnson and Johnson & Johnson  
Consumer Inc.*